

110TH CONGRESS
1ST SESSION

S. 1082

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food and Drug Ad-
5 ministration Revitalization Act”.

1 **TITLE I—PRESCRIPTION DRUG**
2 **USER FEES**

3 **SEC. 101. SHORT TITLE; REFERENCES IN TITLE.**

4 (a) SHORT TITLE.—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2007”.

6 (b) REFERENCES IN TITLE.—Except as otherwise
7 specified, whenever in this title an amendment is ex-
8 pressed in terms of an amendment to a section or other
9 provision, the reference shall be considered to be made to
10 a section or other provision of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 301 et seq.).

12 **SEC. 102. DRUG FEES.**

13 Section 735 (21 U.S.C. 379g) is amended—

14 (1) by striking the section designation and all
15 that follows through “For purposes of this sub-
16 chapter:” and inserting the following:

17 **“SEC. 735. DRUG FEES.**

18 “(a) PURPOSE.—It is the purpose of this part that
19 the fees authorized under this part be dedicated toward
20 expediting the drug development process, the process for
21 the review of human drug applications, and postmarket
22 drug safety, as set forth in the goals identified for pur-
23 poses of this part in the letters from the Secretary to the
24 Chairman of the Committee on Health, Education, Labor,
25 and Pensions of the Senate and the Chairman of the Com-

1 mittee on Energy and Commerce of the House of Rep-
2 resentatives, as set forth in the Congressional Record.

3 “(b) REPORTS.—

4 “(1) PERFORMANCE REPORT.—For fiscal years
5 2008 through 2012, not later than 120 days after
6 the end of each fiscal year during which fees are col-
7 lected under this part, the Secretary shall prepare
8 and submit to the Committee on Health, Education,
9 Labor, and Pensions of the Senate and the Com-
10 mittee on Energy and Commerce of the House of
11 Representatives, a report concerning the progress of
12 the Food and Drug Administration in achieving the
13 goals identified in the letters described in subsection
14 (a) during such fiscal year and the future plans of
15 the Food and Drug Administration for meeting the
16 goals. The report for a fiscal year shall include infor-
17 mation on all previous cohorts for which the Sec-
18 retary has not given a complete response on all
19 human drug applications and supplements in the co-
20 hort.

21 “(2) FISCAL REPORT.—For fiscal years 2008
22 through 2012, not later than 120 days after the end
23 of each fiscal year during which fees are collected
24 under this part, the Secretary shall prepare and sub-
25 mit to the Committee on Health, Education, Labor,

1 and Pensions of the Senate and the Committee on
2 Energy and Commerce of the House of Representa-
3 tives, a report on the implementation of the author-
4 ity for such fees during such fiscal year and the use,
5 by the Food and Drug Administration, of the fees
6 collected during such fiscal year for which the report
7 is made.

8 “(3) PUBLIC AVAILABILITY.—The Secretary
9 shall make the reports required under paragraphs
10 (1) and (2) available to the public on the Internet
11 website of the Food and Drug Administration.

12 “(c) REAUTHORIZATION.—

13 “(1) CONSULTATION.—In developing rec-
14 ommendations to present to Congress with respect to
15 the goals, and plans for meeting the goals, for the
16 process for the review of human drug applications
17 for the first 5 fiscal years after fiscal year 2012, and
18 for the reauthorization of this part for such fiscal
19 years, the Secretary shall consult with—

20 “(A) the Committee on Energy and Com-
21 merce of the House of Representatives;

22 “(B) the Committee on Health, Education,
23 Labor, and Pensions of the Senate;

24 “(C) scientific and academic experts;

25 “(D) health care professionals;

1 “(E) representatives of patient and con-
2 sumer advocacy groups; and

3 “(F) the regulated industry.

4 “(2) PUBLIC REVIEW OF RECOMMENDA-
5 TIONS.—After negotiations with the regulated indus-
6 try, the Secretary shall—

7 “(A) present the recommendations devel-
8 oped under paragraph (1) to the Congressional
9 committees specified in such paragraph;

10 “(B) publish such recommendations in the
11 Federal Register;

12 “(C) provide for a period of 30 days for
13 the public to provide written comments on such
14 recommendations;

15 “(D) hold a meeting at which the public
16 may present its views on such recommenda-
17 tions; and

18 “(E) after consideration of such public
19 views and comments, revise such recommenda-
20 tions as necessary.

21 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
22 Not later than January 15, 2012, the Secretary
23 shall transmit to Congress the revised recommenda-
24 tions under paragraph (2), a summary of the views
25 and comments received under such paragraph, and

any changes made to the recommendations in response to such views and comments.

“(d) DEFINITIONS.—For purposes of this part:”;

(2) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking “505(b)(1),” and inserting “505(b), or”;

(ii) by striking subparagraph (B);

(iii) by redesignating subparagraph (C) as subparagraph (B); and

(iv) in the matter following subparagraph (B), as so redesignated, by striking “subparagraph (C)” and inserting “subparagraph (B)”;

(B) in paragraph (3)(C), by—

(i) striking “the list” and inserting “the list (not including the discontinued section of such list)”;

(ii) striking “a list” and inserting “a list (not including the discontinued section of such a list)”;

(C) in paragraph (4), by inserting before the period at the end the following: “(such as capsules, tablets, and lyophilized products before reconstitution)”;

1 (D) by amending paragraph (6)(F) to read
2 as follows:

3 “(F) In the case of drugs approved under
4 human drug applications or supplements,
5 postmarket safety activities, including—

6 “(i) collecting, developing, and review-
7 ing safety information on approved drugs
8 (including adverse event reports);

9 “(ii) developing and using improved
10 adverse event data collection systems (in-
11 cluding information technology systems);
12 and

13 “(iii) developing and using improved
14 analytical tools to assess potential safety
15 problems (including by accessing external
16 data bases).”;

17 (E) in paragraph (8)—

18 (i) by striking “April of the preceding
19 fiscal year” and inserting “October of the
20 preceding fiscal year”; and

21 (ii) by striking “April 1997” and in-
22 serting “October 1996”;

23 (F) by redesignating paragraph (9) as
24 paragraph (10); and

1 (G) by inserting after paragraph (8) the
 2 following:

3 “(9) The term ‘person’ includes an affiliate of
 4 such person.”.

5 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

6 (a) TYPES OF FEES.—Section 736(a) (21 U.S.C.
 7 379h(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
 9 striking “2003” and inserting “2008”;

10 (2) in paragraph (1)—

11 (A) in subparagraph (D)—

12 (i) in the heading, by inserting “OR
 13 WITHDRAWN BEFORE FILING” after “RE-
 14 FUND OF FEE IF APPLICATION REFUSED
 15 FOR FILING”; and

16 (ii) by inserting before the period at
 17 the end the following: “or withdrawn with-
 18 out a waiver before filing”;

19 (B) by redesignating subparagraphs (E)
 20 and (F) as subparagraphs (F) and (G), respec-
 21 tively; and

22 (C) by inserting after subparagraph (D)
 23 the following:

24 “(E) FEE FOR APPLICATION PREVIOUSLY
 25 REFUSED FOR FILING OR WITHDRAWN BEFORE

FILING.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D).”; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking “subparagraph (B)” and inserting “subparagraphs (B) and (C)”; and

(B) by adding at the end the following:

“(C) SPECIAL RULES FOR COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

“(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a compounded positron emission tomography drug shall be subject under subparagraph (A) to one-fifth of an annual establishment fee with respect to each such establishment identi-

1 fied in the application as producing com-
2 pounded positron emission tomography
3 drugs under the approved application.

4 “(ii) EXCEPTION FROM ANNUAL ES-
5 TABLISHMENT FEE.—Each person who is
6 named as the applicant in an application
7 described in clause (i) shall not be assessed
8 an annual establishment fee for a fiscal
9 year if the person certifies to the Sec-
10 retary, at a time specified by the Secretary
11 and using procedures specified by the Sec-
12 retary, that—

13 “(I) the person is a not-for-profit
14 medical center that has only 1 estab-
15 lishment for the production of com-
16 pounded positron emission tomog-
17 raphy drugs; and

18 “(II) at least 95 percent of the
19 total number of doses of each com-
20 pounded positron emission tomog-
21 raphy drug produced by such estab-
22 lishment during such fiscal year will
23 be used within the medical center.”.

24 (b) FEE REVENUE AMOUNTS.—Section 736(b) (21
25 U.S.C. 379h(b)) is amended to read as follows:

1 “(b) FEE REVENUE AMOUNTS.—Except as provided
2 in subsections (c), (d), (f), and (g), fees under subsection
3 (a) shall be established to generate the following revenue
4 amounts, in each fiscal year beginning with fiscal year
5 2008 and continuing through fiscal year 2012:
6 \$392,783,000, plus an adjustment for workload on
7 \$354,893,000 of this amount. Such adjustment shall be
8 made in accordance with the workload adjustment provi-
9 sions in effect for fiscal year 2007, except that instead
10 of commercial investigational new drug applications sub-
11 mitted to the Secretary, all commercial investigational new
12 drug applications with a submission during the previous
13 12-month period shall be used in the determination. One-
14 third of the revenue amount shall be derived from applica-
15 tion fees, one-third from establishment fees, and one-third
16 from product fees.”.

17 (c) ADJUSTMENTS TO FEES.—

18 (1) INFLATION ADJUSTMENT.—Section
19 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

20 (A) in the matter preceding subparagraph

21 (A) by striking “The revenues established in
22 subsection (b)” and inserting “Beginning with
23 fiscal year 2009, the revenues established in
24 subsection (b)”;

1 (B) in subparagraph (A) by striking “or”
2 at the end;

3 (C) in subparagraph (B) by striking the
4 period at the end and inserting “, or,”;

5 (D) by inserting after subparagraph (B)
6 the following:

7 “(C) the average annual change in the
8 cost, per full-time equivalent position of the
9 Food and Drug Administration, of all personnel
10 compensation and benefits paid with respect to
11 such positions, for the first 5 fiscal years of the
12 previous 6 fiscal years.”; and

13 (E) in the matter following subparagraph
14 (C) (as added by this paragraph), by striking
15 “fiscal year 2003” and inserting “fiscal year
16 2008”.

17 (2) WORKLOAD ADJUSTMENT.—Section
18 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

19 (A) in the matter preceding subparagraph
20 (A,) by striking “2004” and inserting “2009”;

21 (B) in the first sentence of subparagraph
22 (A)—

23 (i) by striking “, commercial inves-
24 tigational new drug applications” and in-

1 serting “(adjusted for changes in review
2 activities)”; and

3 (ii) by inserting before the period at
4 the end “, and the change in the number
5 of commercial investigational new drug ap-
6 plications with a submission during the
7 previous 12-month period (adjusted for
8 changes in review activities)”; and

9 (C) in subparagraph (B), by adding at the
10 end the following new sentence: “Further, any
11 adjustment for changes in review activities
12 made in setting fees and fee revenue amounts
13 for fiscal year 2009 may not result in the total
14 workload adjustment being more than 2 per-
15 centage points higher than it would be absent
16 the adjustment for changes in review activi-
17 ties.”; and

18 (D) by adding at the end the following:

19 “(C) The Secretary shall contract with an
20 independent accounting firm to study the ad-
21 justment for changes in review activities applied
22 in setting fees for fiscal year 2009 and to make
23 recommendations, if warranted, on future
24 changes in the methodology for calculating the
25 adjustment for changes in review activity. After

1 review of the recommendations by the inde-
2 pendent accounting firm, the Secretary shall
3 make appropriate changes to the workload ad-
4 justment methodology in setting fees for fiscal
5 years 2010 through 2012. If the study is not
6 conducted, no adjustment for changes in review
7 activities shall be made after fiscal year 2009.”.

8 (3) RENT AND RENT-RELATED COST ADJUST-
9 MENT.—Section 736(c) (21 U.S.C. 379h(c)) is
10 amended—

11 (A) by redesignating paragraphs (3), (4),
12 and (5) as paragraphs (4), (5), and (6), respec-
13 tively; and

14 (B) by inserting after paragraph (2) the
15 following:

16 “(3) RENT AND RENT-RELATED COST ADJUST-
17 MENT.—Beginning with fiscal year 2010, the Sec-
18 retary shall, before making the adjustments under
19 paragraphs (1) and (2), reduce the fee amounts es-
20 tablished in subsection (b), if actual costs paid for
21 rent and rent-related expenses are less than
22 \$11,721,000. The reductions made under this para-
23 graph, if any, shall not exceed the amounts by which
24 costs fell below \$11,721,000, and shall not exceed
25 \$11,721,000 in any fiscal year.”.

1 (4) FINAL YEAR ADJUSTMENT.—Section 736(c)
2 (21 U.S.C. 379h(c)) is amended—

3 (A) in paragraph (4), as redesignated by
4 this subsection—

5 (i) by striking “2007” each place it
6 appears and inserting “2012”; and

7 (ii) by striking “2008” and inserting
8 “2013”; and

9 (B) in paragraph (5), as redesignated by
10 this subsection, by striking “2002” and insert-
11 ing “2007”.

12 (d) FEE WAIVER OR REDUCTION.—Section 736(d)
13 (21 U.S.C. 379h(d)) is amended—

14 (1) in paragraph (1), in the matter preceding
15 subparagraph (A), by—

16 (A) inserting “to a person who is named as
17 the applicant” after “The Secretary shall
18 grant”;

19 (B) inserting “to that person” after “a
20 waiver from or a reduction of one or more fees
21 assessed”; and

22 (C) striking “finds” and inserting “deter-
23 mines”;

24 (2) by redesignating paragraphs (2) and (3) as
25 paragraphs (3) and (4), respectively;

1 (3) by inserting after paragraph (1) the fol-
 2 lowing:

3 “(2) EVALUATION.—For the purpose of deter-
 4 mining whether to grant a waiver or reduction of a
 5 fee under paragraph (1), the Secretary shall con-
 6 sider only the circumstances and assets of the appli-
 7 cant and any affiliate of the applicant.”; and

8 (4) in paragraph (4), as redesignated by this
 9 subsection, in subparagraph (A), by inserting before
 10 the period at the end “, and that does not have a
 11 drug product that has been approved under a human
 12 drug application and introduced or delivered for in-
 13 troduction into interstate commerce”.

14 (e) CREDITING AND AVAILABILITY OF FEES.—

15 (1) AUTHORIZATION OF APPROPRIATIONS.—
 16 Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amend-
 17 ed to read as follows:

18 “(3) AUTHORIZATION OF APPROPRIATIONS.—
 19 There are authorized to be appropriated for fees
 20 under this section such sums as are authorized to be
 21 assessed and collected under this section in each of
 22 fiscal years 2008 through 2012.”.

23 (2) OFFSET.—Section 736(g)(4) (21 U.S.C.
 24 379h(g)(4)) is amended to read as follows:

1 “(4) OFFSET.—If the cumulative amount of
2 fees collected during fiscal years 2008, 2009, and
3 2010, plus the amount estimated to be collected for
4 fiscal year 2011, exceeds the amount of fees speci-
5 fied in aggregate in appropriation Acts for such fis-
6 cal years, the aggregate amount in excess shall be
7 credited to the appropriation account of the Food
8 and Drug Administration as provided in paragraph
9 (1), and shall be subtracted from the amount of fees
10 that would otherwise be authorized to be collected
11 under this section pursuant to appropriation Acts
12 for fiscal year 2012.”.

13 (f) CONFORMING AMENDMENTS.—

14 (1) Section 736(a) (21 U.S.C. 379h(a)), as
15 amended by this section, is amended—

16 (A) in paragraph (1)(A), by striking “sub-
17 section (c)(4)” each place it appears and insert-
18 ing “subsection (c)(5)”;

19 (B) in paragraph (2), by striking “sub-
20 section (c)(4)” and inserting “subsection
21 (c)(5)”;

22 (C) in paragraph (3), by striking “sub-
23 section (c)(4)” and inserting “subsection
24 (c)(5)”.

1 (2) Section 736A(h)(3), as added by section
 2 104 of this title, is amended by striking “735(3)”
 3 and inserting “735(d)(3)”.

4 **SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION**
 5 **DRUG ADVERTISING FEES.**

6 Chapter VII, subchapter C, part 2 (21 U.S.C. 379g
 7 et seq.) is amended by adding after section 736 the fol-
 8 lowing new section:

9 **“SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE**
 10 **ADVISORY REVIEW OF PRESCRIPTION DRUG**
 11 **ADVERTISING.**

12 “(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION
 13 ADVERTISEMENT REVIEW FEES.—Beginning with fiscal
 14 year 2008, the Secretary shall assess and collect fees in
 15 accordance with this section as follows:

16 “(1) ADVISORY REVIEW FEE.—

17 “(A) IN GENERAL.—Except as provided in
 18 subparagraph (B), each person that on or after
 19 October 1, 2007, submits a proposed direct-to-
 20 consumer television advertisement for advisory
 21 review by the Secretary prior to its initial public
 22 dissemination shall be subject to a fee estab-
 23 lished under subsection (c)(3).

24 “(B) EXCEPTION FOR REQUIRED SUBMIS-
 25 SIONS.—A direct-to-consumer television adver-

1 tisement that is required to be submitted to the
2 Secretary prior to initial public dissemination
3 shall not be assessed a fee unless the sponsor
4 designates it as a submission for advisory re-
5 view.

6 “(C) PAYMENT.—The fee required by sub-
7 paragraph (A) shall be due not later than Octo-
8 ber 1 of the fiscal year in which the direct-to-
9 consumer television advertisement shall be sub-
10 mitted to the Secretary for advisory review.

11 “(D) MODIFICATION OF ADVISORY REVIEW
12 FEE.—

13 “(i) LATE PAYMENT.—If, on or before
14 November 1 of the fiscal year in which the
15 fees are due, a person has not paid all fees
16 that were due and payable for advisory re-
17 views identified in response to the Federal
18 Register notice described in subsection
19 (c)(3)(A), the fees shall be regarded as
20 late. Such fees shall be due and payable 20
21 days before any direct-to-consumer tele-
22 vision advertisement is submitted by such
23 person to the Secretary for advisory re-
24 view. Notwithstanding any other provision
25 of this section, such fees shall be due and

1 payable for each of those advisory reviews
2 in the amount of 150 percent of the advi-
3 sory review fee established for that fiscal
4 year pursuant to subsection (c)(3).

5 “(ii) LATE NOTICE OF SUBMISSION.—

6 If any person submits any direct-to-con-
7 sumer television advertisements for advi-
8 sory review that are in excess of the num-
9 ber identified by that person in response to
10 the Federal Register notice described in
11 subsection (c)(3)(A), that person must pay
12 a fee for each of those advisory reviews in
13 the amount of 150 percent of the advisory
14 review fee established for that fiscal year
15 pursuant to subsection (c)(3). Fees under
16 this subparagraph shall be due 20 days be-
17 fore the direct-to-consumer television ad-
18 vertisement is submitted by such person to
19 the Secretary for advisory review.

20 “(E) LIMITS.—

21 “(i) IN GENERAL.—The payment of a
22 fee under this paragraph for a fiscal year
23 entitles the person that pays the fee to ac-
24 ceptance for advisory review by the Sec-
25 retary of 1 direct-to-consumer television

1 advertisement and acceptance of 1 resub-
2 mission for advisory review of the same ad-
3 vertisement. The advertisement shall be
4 submitted for review in the fiscal year for
5 which the fee was assessed, except that a
6 person may carry over no more than 1
7 paid advisory review submission to the next
8 fiscal year. Resubmissions may be sub-
9 mitted without regard to the fiscal year of
10 the initial advisory review submission.

11 “(ii) NO REFUND.—Except as pro-
12 vided by subsection (f), fees paid under
13 this paragraph shall not be refunded.

14 “(iii) NO WAIVER, EXEMPTION, OR
15 REDUCTION.—The Secretary shall not
16 grant a waiver, exemption, or reduction of
17 any fees due or payable under this section.

18 “(iv) NON-TRANSFERABILITY.—The
19 right to an advisory review is not transfer-
20 able, except to a successor in interest.

21 “(2) OPERATING RESERVE FEE.—

22 “(A) IN GENERAL.—Each person that, on
23 or after October 1, 2007, is assessed an advi-
24 sory review fee under paragraph (1) shall be
25 subject to an operating reserve fee established

1 under subsection (d)(2) only in the first fiscal
2 year in which an advisory review fee is assessed.

3 “(B) PAYMENT.—Except as provided in
4 subparagraph (C), the fee required by subpara-
5 graph (A) shall be due not later than October
6 1 of the first fiscal year in which the person is
7 required to pay an advisory review fee under
8 paragraph (1).

9 “(C) LATE NOTICE OF SUBMISSION.—If, in
10 the first fiscal year of a person’s participation
11 in the Program, that person submits any direct-
12 to-consumer television advertisements for advi-
13 sory review that are in excess of the number
14 identified by that person in response to the
15 Federal Register notice described in subsection
16 (c)(3)(A), that person must pay an operating
17 reserve fee for each of those advisory reviews
18 equal to the advisory review fee for each sub-
19 mission established under paragraph (1)(D)(ii).
20 Fees required by this subparagraph shall be in
21 addition to the fees required under subpara-
22 graph (B), if any. Fees under this subpara-
23 graph shall be due 20 days before any direct-
24 to-consumer television advertisement is sub-

1 mitted by such person to the Secretary for advi-
2 sory review.

3 “(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—
4 Fees under subsection (a)(1) shall be established to gen-
5 erate revenue amounts of \$6,250,000 for each of fiscal
6 years 2008 through 2012, as adjusted pursuant to sub-
7 section (c).

8 “(c) ADJUSTMENTS.—

9 “(1) INFLATION ADJUSTMENT.—Beginning
10 with fiscal year 2009, the revenues established in
11 subsection (b) shall be adjusted by the Secretary by
12 notice, published in the Federal Register, for a fiscal
13 year to reflect the greater of—

14 “(A) the total percentage change that oc-
15 curred in the Consumer Price Index for all
16 urban consumers (all items; United States city
17 average), for the 12-month period ending June
18 30 preceding the fiscal year for which fees are
19 being established;

20 “(B) the total percentage change for the
21 previous fiscal year in basic pay under the Gen-
22 eral Schedule in accordance with section 5332
23 of title 5, as adjusted by any locality-based
24 comparability payment pursuant to section

1 5304 of such title for Federal employees sta-
2 tioned in the District of Columbia; or

3 “(C) the average annual change in the
4 cost, per full-time equivalent position of the
5 Food and Drug Administration, of all personnel
6 compensation and benefits paid with respect to
7 such positions, for the first 5 fiscal years of the
8 previous 6 fiscal years.

9 The adjustment made each fiscal year by this para-
10 graph shall be added on a compounded basis to the
11 sum of all adjustments made each fiscal year after
12 fiscal year 2008 under this subsection.

13 “(2) WORKLOAD ADJUSTMENT.—

14 “(A) IN GENERAL.—Beginning with fiscal
15 year 2009, after the fee revenues established in
16 subsection (b) of this section are adjusted for a
17 fiscal year for inflation in accordance with para-
18 graph (1), the fee revenues shall be adjusted
19 further for such fiscal year to reflect changes in
20 the workload of the Secretary with respect to
21 the submission of proposed direct-to-consumer
22 television advertisements for advisory review
23 prior to initial broadcast.

24 “(B) DETERMINATION OF WORKLOAD AD-
25 JUSTMENT.—

1 “(i) IN GENERAL.—The workload ad-
2 justment under this paragraph for a fiscal
3 year shall be determined by the Sec-
4 retary—

5 “(I) based upon the number of
6 direct-to-consumer television adver-
7 tisements identified pursuant to para-
8 graph (3)(A) for that fiscal year, ex-
9 cluding allowable previously paid carry
10 over submissions; and

11 “(II) by multiplying the number
12 of such advertisements projected for
13 that fiscal year that exceeds 150 by
14 \$27,600 (adjusted each year begin-
15 ning with fiscal year 2009 for infla-
16 tion in accordance with paragraph
17 (1)).

18 “(ii) PUBLICATION IN FEDERAL REG-
19 ISTER.—The Secretary shall publish in the
20 Federal Register, as part of the notice de-
21 scribed in paragraph (1), the fee revenues
22 and fees resulting from the adjustment
23 made under this paragraph and the sup-
24 porting methodologies.

1 “(C) LIMITATION.—Under no cir-
2 cumstances shall the adjustment made under
3 this paragraph result in fee revenues for a fiscal
4 year that are less than the fee revenues estab-
5 lished for the prior fiscal year.

6 “(3) ANNUAL FEE SETTING.—

7 “(A) NUMBER OF ADVERTISEMENTS.—The
8 Secretary shall, 120 days before the start of
9 each fiscal year, publish a notice in the Federal
10 Register requesting any person to notify the
11 Secretary within 30 days of the number of di-
12 rect-to-consumer television advertisements the
13 person intends to submit for advisory review by
14 the Secretary in the next fiscal year. Notifica-
15 tion to the Secretary of the number of adver-
16 tisements a person intends to submit for advi-
17 sory review prior to initial broadcast shall be a
18 legally binding commitment by that person to
19 pay the annual advisory review fee for that
20 number of submissions on or before October 1
21 of the fiscal year in which the advertisement is
22 intended to be submitted. A person shall at the
23 same time also notify the Secretary if such per-
24 son intends to use a paid submission from the
25 previous fiscal year under subsection

1 (a)(1)(E)(i). If such person does not so notify
2 the Secretary, all submissions for advisory re-
3 view shall be subject to advisory review fees.

4 “(B) ANNUAL FEE.—The Secretary shall,
5 60 days before the start of each fiscal year, es-
6 tablish, for the next fiscal year, the direct-to-
7 consumer television advertisement advisory re-
8 view fee under subsection (a)(1), based on the
9 revenue amounts established under subsection
10 (b), the adjustments provided under this sub-
11 section and the number of direct-to-consumer
12 television advertisements identified pursuant to
13 subparagraph (A), excluding allowable pre-
14 viously paid carry over submissions. The annual
15 advisory review fee shall be established by divid-
16 ing the fee revenue for a fiscal year (as ad-
17 justed pursuant to this subsection) by the num-
18 ber of direct-to-consumer television advertise-
19 ments identified pursuant to subparagraph (A),
20 excluding allowable previously paid carry over
21 submissions.

22 “(C) FISCAL YEAR 2008 FEE LIMIT.—Not-
23 withstanding subsection (b), the fee established
24 under subparagraph (B) for fiscal year 2008

1 may not be more than \$83,000 per submission
2 for advisory review.

3 “(D) ANNUAL FEE LIMIT.—Notwith-
4 standing subsection (b), the fee established
5 under subparagraph (B) for a fiscal year after
6 fiscal year 2008 may not be more than 50 per-
7 cent more than the fee established for the prior
8 fiscal year.

9 “(E) LIMIT.—The total amount of fees ob-
10 ligated for a fiscal year may not exceed the
11 total costs for such fiscal year for the resources
12 allocated for the process for the advisory review
13 of prescription drug advertising.

14 “(d) OPERATING RESERVES.—

15 “(1) IN GENERAL.—The Secretary shall estab-
16 lish in the Food and Drug Administration salaries
17 and expenses appropriation account without fiscal
18 year limitation a Direct-to-Consumer Advisory Re-
19 view Operating Reserve, of at least \$6,250,000 in
20 fiscal year 2008, to continue the Program in the
21 event the fees collected in any subsequent fiscal year
22 pursuant to subsection (c)(3) do not generate the fee
23 revenue amount established for that fiscal year.

24 “(2) FEE SETTING.—The Secretary shall estab-
25 lish the operating reserve fee under subsection

1 (a)(2)(A) for each person required to pay the fee by
2 multiplying the number of direct-to-consumer tele-
3 vision advertisements identified by that person pur-
4 suant to subsection (c)(3)(A) by the advisory review
5 fee established pursuant to subsection (c)(3) for that
6 fiscal year. In no case shall the operating reserve fee
7 assessed be less than the operating reserve fee as-
8 sessed if the person had first participated in the
9 Program in fiscal year 2008.

10 “(3) USE OF OPERATING RESERVE.—The Sec-
11 retary may use funds from the reserves under this
12 subsection only to the extent necessary in any fiscal
13 year to make up the difference between the fee rev-
14 enue amount established for that fiscal year under
15 subsection (b) and the amount of fees collected for
16 that fiscal year pursuant to subsection (a), or to pay
17 costs of ending the Program if it is terminated pur-
18 suant to subsection (f) or if it is not reauthorized
19 after fiscal year 2012.

20 “(4) REFUND OF OPERATING RESERVES.—
21 Within 120 days of the end of fiscal year 2012, or
22 if the Program is terminated pursuant to subsection
23 (f), the Secretary, after setting aside sufficient oper-
24 ating reserve amounts to terminate the Program,
25 shall refund all amounts remaining in the operating

1 reserve on a pro rata basis to each person that paid
2 an operating reserve fee assessment. In no event
3 shall the refund to any person exceed the total
4 amount of operating reserve fees paid by such per-
5 son pursuant to subsection (a)(2).

6 “(e) EFFECT OF FAILURE TO PAY FEES.—Notwith-
7 standing any other law or regulation of the Secretary, a
8 submission for advisory review of a direct-to-consumer tel-
9 evision advertisement submitted by a person subject to
10 fees under subsection (a) shall be considered incomplete
11 and shall not be accepted for review by the Secretary until
12 all fees owed by such person under this section have been
13 paid.

14 “(f) EFFECT OF INADEQUATE FUNDING OF PRO-
15 GRAM.—

16 “(1) FIRST FISCAL YEAR.—If on November 1,
17 2007, or 120 days after enactment of the Prescrip-
18 tion Drug User Fee Amendments of 2007, whichever
19 is later, the Secretary has received less than
20 \$11,250,000 in advisory review fees and operating
21 reserve fees combined, the Program shall be termi-
22 nated and all collected fees shall be refunded.

23 “(2) SUBSEQUENT FISCAL YEARS.—Beginning
24 in fiscal year 2009, if, on November 1 of a fiscal
25 year, the combination of the operating reserves, an-

1 nual fee revenues from that fiscal year, and unobli-
2 gated fee revenues from prior fiscal years is less
3 than \$9,000,000, adjusted for inflation (in accord-
4 ance with subsection (c)(1)), the Program shall be
5 terminated, and the Secretary shall notify all partici-
6 pants, retain any money from the unused advisory
7 review fees and the operating reserves needed to ter-
8 minate the Program, and refund the remainder of
9 the unused fees and operating reserves. To the ex-
10 tent required to terminate the Program, the Sec-
11 retary shall first use unobligated advisory review fee
12 revenues from prior fiscal years, then the operating
13 reserves, and then unused advisory review fees from
14 the relevant fiscal year.

15 “(g) CREDITING AND AVAILABILITY OF FEES.—

16 “(1) IN GENERAL.—Fees authorized under sub-
17 section (a) shall be collected and available for obliga-
18 tion only to the extent and in the amount provided
19 in advance in appropriations Acts. Such fees are au-
20 thorized to remain available until expended. Such
21 sums as may be necessary may be transferred from
22 the Food and Drug Administration salaries and ex-
23 penses appropriation account without fiscal year lim-
24 itation to such appropriation account for salaries
25 and expenses with such fiscal year limitation. The

1 sums transferred shall be available solely for the
2 process for the advisory review of prescription drug
3 advertising.

4 “(2) COLLECTIONS AND APPROPRIATION
5 ACTS.—The fees authorized by this section—

6 “(A) shall be retained in each fiscal year in
7 an amount not to exceed the amount specified
8 in appropriation Acts, or otherwise made avail-
9 able for obligation for such fiscal year; and

10 “(B) shall be available for obligation only
11 if appropriated budget authority continues to
12 support at least the total combined number of
13 full-time equivalent employees in the Food and
14 Drug Administration, Center for Drug Evalua-
15 tion and Research, Division of Drug Marketing,
16 Advertising, and Communications, and the Cen-
17 ter for Biologics Evaluation and Research, Ad-
18 vertising and Promotional Labeling Branch
19 supported in fiscal year 2007.

20 “(3) AUTHORIZATION OF APPROPRIATIONS.—

21 There are authorized to be appropriated for fees
22 under this section not less than \$6,250,000 for each
23 of fiscal years 2008, 2009, 2010, 2011, and 2012,
24 as adjusted to reflect adjustments in the total fee

1 revenues made under this section, plus amounts col-
2 lected for the reserve fund under subsection (d).

3 “(4) OFFSET.—Any amount of fees collected
4 for a fiscal year under this section that exceeds the
5 amount of fees specified in appropriation Acts for
6 such fiscal year shall be credited to the appropria-
7 tion account of the Food and Drug Administration
8 as provided in paragraph (1), and shall be sub-
9 tracted from the amount of fees that would other-
10 wise be collected under this section pursuant to ap-
11 propriation Acts for a subsequent fiscal year.

12 “(h) DEFINITIONS.—For purposes of this section:

13 “(1) The term ‘advisory review’ means review-
14 ing and providing advisory comments regarding com-
15 pliance of a proposed advertisement with the re-
16 quirements of this Act prior to its initial public dis-
17 semination.

18 “(2) The term ‘carry over submission’ means a
19 submission for an advisory review for which a fee
20 was paid in a fiscal year that is submitted for review
21 in the following fiscal year.

22 “(3) The term ‘direct-to-consumer television ad-
23 vertisement’ means an advertisement for a prescrip-
24 tion drug product as defined in section 735(3) in-

1 tended to be displayed on any television channel for
2 less than 2 minutes.

3 “(4) The term ‘person’ includes an individual,
4 a partnership, a corporation, and an association, and
5 any affiliate thereof or successor in interest.

6 “(5) The term ‘process for the advisory review
7 of prescription drug advertising’ means the activities
8 necessary to review and provide advisory comments
9 on proposed direct-to-consumer television advertise-
10 ments prior to public dissemination and, to the ex-
11 tent the Secretary has additional staff resources
12 available under the Program that are not necessary
13 for the advisory review of direct-to-consumer tele-
14 vision advertisements, the activities necessary to re-
15 view and provide advisory comments on other pro-
16 posed advertisements and promotional material prior
17 to public dissemination.

18 “(6) The term ‘Program’ means the Program
19 to assess, collect, and use fees for the advisory re-
20 view of prescription drug advertising established by
21 this section.

22 “(7) The term ‘resources allocated for the proc-
23 ess for the advisory review of prescription drug ad-
24 vertising’ means the expenses incurred in connection

1 with the process for the advisory review of prescrip-
2 tion drug advertising for—

3 “(A) officers and employees of the Food
4 and Drug Administration, contractors of the
5 Food and Drug Administration, advisory com-
6 mittees, and costs related to such officers, em-
7 ployees, and committees, and to contracts with
8 such contractors;

9 “(B) management of information, and the
10 acquisition, maintenance, and repair of com-
11 puter resources;

12 “(C) leasing, maintenance, renovation, and
13 repair of facilities and acquisition, maintenance,
14 and repair of fixtures, furniture, scientific
15 equipment, and other necessary materials and
16 supplies;

17 “(D) collection of fees under this section
18 and accounting for resources allocated for the
19 advisory review of prescription drug advertising;
20 and

21 “(E) terminating the Program under sub-
22 section (f)(2), if necessary.

23 “(8) The term ‘resubmission’ means a subse-
24 quent submission for advisory review of a direct-to-
25 consumer television advertisement that has been re-

1 vised in response to the Secretary’s comments on an
2 original submission. A resubmission may not intro-
3 duce significant new concepts or creative themes into
4 the television advertisement.

5 “(9) The term ‘submission for advisory review’
6 means an original submission of a direct-to-con-
7 sumer television advertisement for which the sponsor
8 voluntarily requests advisory comments before the
9 advertisement is publicly disseminated.

10 **“SEC. 736B. SUNSET.**

11 “‘This part shall cease to be effective on October 1,
12 2012, except that subsection (b) of section 736 with re-
13 spect to reports shall cease to be effective on January 31,
14 2013.’”.

15 **SEC. 105. SAVINGS CLAUSE.**

16 Notwithstanding section 509 of the Prescription
17 Drug User Fee Amendments of 2002 (21 U.S.C. 379g
18 note), and notwithstanding the amendments made by this
19 title, part 2 of subchapter C of chapter VII of the Federal
20 Food, Drug, and Cosmetic Act, as in effect on the day
21 before the date of enactment of this title, shall continue
22 to be in effect with respect to human drug applications
23 and supplements (as defined in such part as of such day)
24 that on or after October 1, 2002, but before October 1,
25 2007, were accepted by the Food and Drug Administra-

tion for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 106. TECHNICAL AMENDMENT.

Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1), by striking “subchapter” and inserting “part”.

SEC. 107. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided in subsection (b), the amendments made by this title shall take effect October 1, 2007.

(b) EXCEPTION.—The amendment made by section 104 of this title shall take effect on the date of enactment of this title.

TITLE II—DRUG SAFETY

SEC. 200. SHORT TITLE.

This title may be cited as the “Enhancing Drug Safety and Innovation Act of 2007”.

Subtitle A—Risk Evaluation and Mitigation Strategies

SEC. 201. ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

1 “(3) ROUTINE ACTIVE SURVEILLANCE AND AS-
2 SESSMENT.—

3 “(A) DEVELOPMENT OF THE POSTMARKET
4 RISK IDENTIFICATION AND ANALYSIS SYS-
5 TEM.—The Secretary shall, not later than 2
6 years after the date of enactment of the En-
7 hancing Drug Safety and Innovation Act of
8 2007, act in collaboration with academic insti-
9 tutions and private entities to—

10 “(i) establish minimum standards for
11 collection and transmission of post-
12 marketing data elements from electronic
13 health data systems; and

14 “(ii) establish, through partnerships,
15 a validated and integrated postmarket risk
16 identification and analysis system to inte-
17 grate and analyze safety data from mul-
18 tiple sources, with the goals of including,
19 in aggregate—

20 “(I) at least 25,000,000 patients
21 by July 1, 2010; and

22 “(II) at least 100,000,000 pa-
23 tients by July 1, 2012.

24 “(B) DATA COLLECTION ACTIVITIES.—

1 “(i) IN GENERAL.—The Secretary
2 shall, not later than 1 year after the estab-
3 lishment of the minimum standards and
4 the identification and analysis system
5 under subparagraph (A), establish and
6 maintain an active surveillance infrastruc-
7 ture—

8 “(I) to collect and report data for
9 pharmaceutical postmarket risk iden-
10 tification and analysis, in compliance
11 with the regulations promulgated
12 under section 264(c) of the Health In-
13 surance Portability and Accountability
14 Act of 1996; and

15 “(II) that includes, in addition to
16 the collection and monitoring (in a
17 standardized form) of data on all seri-
18 ous adverse drug experiences (as de-
19 fined in subsection (o)(2)(C)) required
20 to be submitted to the Secretary
21 under paragraph (1), and those events
22 voluntarily submitted from patients,
23 providers, and drug, when appro-
24 priate, procedures to—

1 “(aa) provide for adverse
2 event surveillance by collecting
3 and monitoring Federal health-
4 related electronic data (such as
5 data from the Medicare program
6 and the health systems of the
7 Department of Veterans Affairs);

8 “(bb) provide for adverse
9 event surveillance by collecting
10 and monitoring private sector
11 health-related electronic data
12 (such as pharmaceutical purchase
13 data and health insurance claims
14 data);

15 “(cc) provide for adverse
16 event surveillance by monitoring
17 standardized electronic health
18 records, as available;

19 “(dd) provide for adverse
20 event surveillance by collecting
21 and monitoring other information
22 as the Secretary deems necessary
23 to create a robust system to iden-
24 tify adverse events and potential
25 drug safety signals;

1 “(ee) enable the program to
2 identify certain trends and pat-
3 terns with respect to data re-
4 ported to the program;

5 “(ff) enable the program to
6 provide regular reports to the
7 Secretary concerning adverse
8 event trends, adverse event pat-
9 terns, incidence and prevalence of
10 adverse events, laboratory data,
11 and other information determined
12 appropriate, which may include
13 data on comparative national ad-
14 verse event trends; and

15 “(gg) enable the program to
16 export data in a form appropriate
17 for further aggregation, statis-
18 tical analysis, and reporting.

19 “(ii) TIMELINESS OF REPORTING.—
20 The procedures developed under clause (i)
21 shall ensure that such data are collected,
22 monitored, and reported in a timely, rou-
23 tine, and automatic manner, taking into
24 consideration the need for data complete-
25 ness, coding, cleansing, and transmission.

1 “(iii) PRIVATE SECTOR RESOURCES.—

2 To ensure the establishment of the active
3 surveillance infrastructure by the date de-
4 scribed under clause (i), the Secretary
5 may, on a temporary or permanent basis,
6 implement systems or products developed
7 by private entities.

8 “(iv) COMPLEMENTARY AP-
9 PROACHES.—To the extent the active sur-
10 veillance infrastructure established under
11 clause (i) is not sufficient to gather data
12 and information relevant to priority drug
13 safety questions, the Secretary shall de-
14 velop, support, and participate in com-
15 plementary approaches to gather and ana-
16 lyze such data and information, includ-
17 ing—

18 “(I) approaches that are com-
19 plementary with respect to assessing
20 the safety of use of a drug in domestic
21 populations not included in the trials
22 used to approve the drug (such as
23 older people, people with
24 comorbidities, pregnant women, or
25 children); and

1 “(II) existing approaches such as
2 the Vaccine Adverse Event Reporting
3 System and the Vaccine Safety
4 Datalink or successor databases.

5 “(v) AUTHORITY FOR CONTRACTS.—
6 The Secretary may enter into contracts
7 with public and private entities to fulfill
8 the requirements of this subparagraph.

9 “(C) RISK IDENTIFICATION AND ANAL-
10 YSIS.—

11 “(i) PURPOSE.—To carry out this
12 paragraph, the Secretary shall establish
13 collaborations with other Government, aca-
14 demic, and private entities, including the
15 Centers for Education and Research on
16 Therapeutics under section 912 of the
17 Public Health Service Act, to provide for
18 the risk identification and analysis of the
19 data collected under subparagraph (B) and
20 data that is publicly available or is pro-
21 vided by the Secretary, in order to—

22 “(I) improve the quality and effi-
23 ciency of postmarket drug safety risk-
24 benefit analysis;

1 “(II) provide the Secretary with
2 routine access to expertise to study
3 advanced drug safety data; and

4 “(III) enhance the ability of the
5 Secretary to make timely assessments
6 based on drug safety data.

7 “(ii) PUBLIC PROCESS FOR PRIORITY
8 QUESTIONS.—At least biannually, the Sec-
9 retary shall seek recommendations from
10 the Drug Safety and Risk Management
11 Advisory Committee (or successor com-
12 mittee) and from other advisory commit-
13 tees, as appropriate, to the Food and Drug
14 Administration on—

15 “(I) priority drug safety ques-
16 tions; and

17 “(II) mechanisms for answering
18 such questions, including through—

19 “(aa) routine active surveil-
20 lance under subparagraph (B);
21 and

22 “(bb) when such surveillance
23 is not sufficient, postmarket
24 studies under subsection
25 (o)(4)(B) and postapproval clin-

1 ical trials under subsection
2 (o)(4)(C).

3 “(iii) PROCEDURES FOR THE DEVEL-
4 OPMENT OF DRUG SAFETY COLLABORA-
5 TIONS.—

6 “(I) IN GENERAL.—Not later
7 than 180 days after the date of the
8 establishment of the active surveil-
9 lance infrastructure under subpara-
10 graph (B), the Secretary shall estab-
11 lish and implement procedures under
12 which the Secretary may routinely col-
13 laborate with a qualified entity to—

14 “(aa) clean, classify, or ag-
15 gregate data collected under sub-
16 paragraph (B) and data that is
17 publicly available or is provided
18 by the Secretary;

19 “(bb) allow for prompt in-
20 vestigation of priority drug safety
21 questions, including—

22 “(AA) unresolved safety
23 questions for drugs or class-
24 es of drugs; and

1 “(BB) for a newly-ap-
2 proved drug: safety signals
3 from clinical trials used to
4 approve the drug and other
5 preapproval trials; rare, seri-
6 ous drug side effects; and
7 the safety of use in domestic
8 populations not included in
9 the trials used to approve
10 the drug (such as older peo-
11 ple, people with
12 comorbidities, pregnant
13 women, or children);
14 “(cc) perform advanced re-
15 search and analysis on identified
16 drug safety risks;
17 “(dd) convene an expert ad-
18 visory committee to oversee the
19 establishment of standards for
20 the ethical and scientific uses for,
21 and communication of, post-
22 marketing data collected under
23 subparagraph (B), including ad-
24 vising on the development of ef-

fective research methods for the
study of drug safety questions;

“(ee) focus postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

“(ff) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

“(II) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in subclause (I) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

1 “(iv) USE OF ANALYSES.—The Sec-
2 retary shall provide the analyses described
3 under this subparagraph, including the
4 methods and results of such analyses,
5 about a drug to the sponsor or sponsors of
6 such drug.

7 “(v) QUALIFIED ENTITIES.—

8 “(I) IN GENERAL.—The Sec-
9 retary shall enter into contracts with
10 a sufficient number of qualified enti-
11 ties to develop and provide informa-
12 tion to the Secretary in a timely man-
13 ner.

14 “(II) QUALIFICATION.—The Sec-
15 retary shall enter into a contract with
16 an entity under subclause (I) only if
17 the Secretary determines that the en-
18 tity—

19 “(aa) has the research capa-
20 bility and expertise to conduct
21 and complete the activities under
22 this paragraph;

23 “(bb) has in place an infor-
24 mation technology infrastructure
25 to support adverse event surveil-

1 lance data and operational stand-
2 ards to provide security for such
3 data;

4 “(cc) has experience with,
5 and expertise on, the develop-
6 ment of drug safety and effec-
7 tiveness research using electronic
8 population data;

9 “(dd) has an understanding
10 of drug development and risk/
11 benefit balancing in a clinical set-
12 ting; and

13 “(ee) has a significant busi-
14 ness presence in the United
15 States.

16 “(vi) CONTRACT REQUIREMENTS.—
17 Each contract with a qualified entity shall
18 contain the following requirements:

19 “(I) ENSURING PRIVACY.—The
20 qualified entity shall provide assur-
21 ances that the entity will not use the
22 data provided by the Secretary in a
23 manner that violates—

24 “(aa) the regulations pro-
25 mulgated under section 264(c) of

1 the Health Insurance Portability
2 and Accountability Act of 1996;
3 or

4 “(bb) sections 552 or 552a
5 of title 5, United States Code,
6 with regard to the privacy of in-
7 dividualy-identifiable beneficiary
8 health information.

9 “(II) COMPONENT OF ANOTHER
10 ORGANIZATION.—If a qualified entity
11 is a component of another organiza-
12 tion—

13 “(aa) the qualified entity
14 shall maintain the data related to
15 the activities carried out under
16 this paragraph separate from the
17 other components of the organi-
18 zation and establish appropriate
19 security measures to maintain
20 the confidentiality and privacy of
21 such data; and

22 “(bb) the entity shall not
23 make an unauthorized disclosure
24 of such data to the other compo-
25 nents of the organization in

1 breach of such confidentiality and
2 privacy requirement.

3 “(III) TERMINATION OR NON-
4 RENEWAL.—If a contract with a
5 qualified entity under this subpara-
6 graph is terminated or not renewed,
7 the following requirements shall apply:

8 “(aa) CONFIDENTIALITY
9 AND PRIVACY PROTECTIONS.—
10 The entity shall continue to com-
11 ply with the confidentiality and
12 privacy requirements under this
13 paragraph with respect to all
14 data disclosed to the entity.

15 “(bb) DISPOSITION OF
16 DATA.—The entity shall return
17 to the Secretary all data dis-
18 closed to the entity or, if return-
19 ing the data is not practicable,
20 destroy the data.

21 “(vii) COMPETITIVE PROCEDURES.—
22 The Secretary shall use competitive proce-
23 dures (as defined in section 4(5) of the
24 Federal Procurement Policy Act) to enter
25 into contracts under clause (v).

1 “(viii) REVIEW OF CONTRACT IN THE
2 EVEN OF A MERGER OR ACQUISITION.—

3 The Secretary shall review the contract
4 with a qualified entity under this para-
5 graph in the event of a merger or acquisi-
6 tion of the entity in order to ensure that
7 the requirements under this subparagraph
8 will continue to be met.

9 “(D) COORDINATION.—In carrying out
10 this paragraph, the Secretary shall provide for
11 appropriate communications to the public, sci-
12 entific, public health, and medical communities,
13 and other key stakeholders, and provide for the
14 coordination of the activities of private entities,
15 professional associations, or other entities that
16 may have sources of surveillance data.”.

17 (b) AUTHORIZATION OF APPROPRIATIONS.—To carry
18 out activities under the amendment made by this section
19 for which funds are made available under section 736 of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 379h), there are authorized to be appropriated to carry
22 out the amendment made by this section, in addition to
23 such funds, \$25,000,000 for each of fiscal years 2008
24 through 2012.

1 **SEC. 202. RISK EVALUATION AND MITIGATION STRATEGIES.**

2 Section 505 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 355) is amended by adding at the end the
4 following:

5 “(o) RISK EVALUATION AND MITIGATION STRAT-
6 EGY.—

7 “(1) IN GENERAL.—In the case of any drug
8 subject to subsection (b) or to section 351 of the
9 Public Health Service Act for which a risk evalua-
10 tion and mitigation strategy is approved as provided
11 for in this subsection, the applicant shall comply
12 with the requirements of such strategy.

13 “(2) DEFINITIONS.—In this subsection:

14 “(A) ADVERSE DRUG EXPERIENCE.—The
15 term ‘adverse drug experience’ means any ad-
16 verse event associated with the use of a drug in
17 humans, whether or not considered drug re-
18 lated, including—

19 “(i) an adverse event occurring in the
20 course of the use of the drug in profes-
21 sional practice;

22 “(ii) an adverse event occurring from
23 an overdose of the drug, whether acci-
24 dental or intentional;

25 “(iii) an adverse event occurring from
26 abuse of the drug;

“(iv) an adverse event occurring from withdrawal of the drug; and

“(v) any failure of expected pharmacological action of the drug.

“(B) NEW SAFETY INFORMATION.—The term ‘new safety information’ with respect to a drug means information about—

“(i) a serious risk or an unexpected serious risk with use of the drug that the Secretary has become aware of since the later of—

“(I) the date of initial approval of the drug under this section or initial licensure of the drug under section 351 of the Public Health Service Act; or

“(II) if applicable, the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

“(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the later of—

“(I) the approval of such strategy; or

1 “(II) the last assessment of such
2 strategy.

3 “(C) SERIOUS ADVERSE DRUG EXPERI-
4 ENCE.—The term ‘serious adverse drug experi-
5 ence’ is an adverse drug experience that—

6 “(i) results in—

7 “(I) death;

8 “(II) the placement of the pa-
9 tient at immediate risk of death from
10 the adverse drug experience as it oc-
11 curred (not including an adverse drug
12 experience that might have caused
13 death had it occurred in a more severe
14 form);

15 “(III) inpatient hospitalization or
16 prolongation of existing hospitaliza-
17 tion;

18 “(IV) a persistent or significant
19 incapacity or substantial disruption of
20 the ability to conduct normal life
21 functions; or

22 “(V) a congenital anomaly or
23 birth defect; or

24 “(ii) based on appropriate medical
25 judgment, may jeopardize the patient and

1 may require a medical or surgical interven-
2 tion to prevent an outcome described under
3 clause (i).

4 “(D) SERIOUS RISK.—The term ‘serious
5 risk’ means a risk of a serious adverse drug ex-
6 perience.

7 “(E) SIGNAL OF A SERIOUS RISK.—The
8 term ‘signal of a serious risk’ means informa-
9 tion related to a serious adverse drug experi-
10 ence derived from—

11 “(i) a clinical trial;

12 “(ii) adverse event reports under sub-
13 section (k)(1);

14 “(iii) routine active surveillance under
15 subsection (k)(3);

16 “(iv) a postapproval study, including a
17 study under paragraph (4)(B); or

18 “(v) peer-reviewed biomedical lit-
19 erature.

20 “(F) UNEXPECTED SERIOUS RISK.—The
21 term ‘unexpected serious risk’ means a serious
22 adverse drug experience that—

23 “(i) is not listed in the labeling of a
24 drug; or

“(ii) is symptomatically and pathophysiologically related to an adverse drug experience listed in the labeling of the drug, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

“(3) REQUIRED ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—If a risk evaluation and mitigation strategy for a drug is required, such strategy shall include—

“(A) the labeling for the drug for use by health care providers as approved under subsection (c);

“(B) a timetable for submission of assessments of the strategy, that—

“(i) for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act—

“(I) shall be no less frequently than 18 months and 3 years after the drug is initially approved and at a fre-

1 quency specified in the strategy for
2 subsequent years; and

3 “(II) may be eliminated after the
4 first 3 years if the Secretary deter-
5 mines that serious risks of the drug
6 have been adequately identified and
7 assessed and are being adequately
8 managed;

9 “(ii) for a drug other than a drug de-
10 scribed under clause (i), shall occur at a
11 frequency determined by the Secretary;
12 and

13 “(iii) may be increased or reduced in
14 frequency as necessary as provided for in
15 paragraph (7)(B)(v)(VI).

16 “(4) ADDITIONAL POTENTIAL EVALUATION
17 ELEMENTS OF A RISK EVALUATION AND MITIGATION
18 STRATEGY.—

19 “(A) RISK EVALUATION.—If a risk evalua-
20 tion and mitigation strategy for a drug is re-
21 quired, such strategy may include 1 or more of
22 the additional evaluation elements described in
23 this paragraph, so long as the Secretary makes
24 the determination required with respect to each
25 additional included element.

1 “(B) POSTAPPROVAL STUDIES.—If the
2 Secretary determines that the reports under
3 subsection (k)(1) and routine active surveillance
4 as available under subsection (k)(3) (including
5 available complementary approaches under sub-
6 section (k)(3)(B)(iv)) will not be sufficient to—

7 “(i) assess a signal of a serious risk
8 with use of a drug; or

9 “(ii) identify, based on a review of a
10 demonstrated pattern of use of the drug,
11 unexpected serious risks in a domestic pop-
12 ulation, including older people, people with
13 comorbidities, pregnant women, or chil-
14 dren,
15 the risk evaluation and mitigation strategy for
16 the drug may require that the applicant con-
17 duct an appropriate postapproval study, such as
18 a prospective or retrospective observational
19 study, of the drug (which shall include a time-
20 frame specified by the Secretary for completing
21 the study and reporting the results to the Sec-
22 retary).

23 “(C) POSTAPPROVAL CLINICAL TRIALS.—If
24 the Secretary determines that the reports under
25 subsection (k)(1), routine active surveillance as

1 available under subsection (k)(3) (including
2 available complementary approaches under sub-
3 section (k)(3)(B)(iv)), and a study or studies
4 under subparagraph (B) will likely be inad-
5 equate to assess a signal of a serious risk with
6 use of a drug, and there is no effective ap-
7 proved application for the drug under sub-
8 section (j) as of the date that the requirement
9 is first imposed, the risk evaluation and mitiga-
10 tion strategy for the drug may require that the
11 applicant conduct an appropriate postapproval
12 clinical trial of the drug (which shall include a
13 timeframe specified by the Secretary for com-
14 pleting the clinical trial and reporting the re-
15 sults to the Secretary) to be included in the
16 clinical trial registry data bank provided for
17 under subsections (i) and (j) of section 402 of
18 the Public Health Service Act.

19 “(5) ADDITIONAL POTENTIAL COMMUNICATION
20 ELEMENTS OF A RISK EVALUATION AND MITIGATION
21 STRATEGY.—

22 “(A) RISK COMMUNICATION.—If a risk
23 evaluation and mitigation strategy for a drug is
24 required, such strategy may include 1 or more
25 of the additional communication elements de-

scribed in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

“(B) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop for distribution to each patient when the drug is dispensed either or both of the following:

“(i) A Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

“(ii) A patient package insert, if the Secretary determines that such insert may help mitigate a serious risk listed in the labeling of the drug.

“(C) COMMUNICATION PLAN.—If the Secretary determines that a communication plan to health care providers may support implementation of an element of the risk evaluation and mitigation strategy for a drug, such as a labeling change, the strategy may require that the applicant conduct such a plan, which may include—

1 “(i) sending letters to health care pro-
2 viders;

3 “(ii) disseminating information about
4 the elements of the strategy to encourage
5 implementation by health care providers of
6 components that apply to such health care
7 providers, or to explain certain safety pro-
8 tocols (such as medical monitoring by peri-
9 odic laboratory tests); or

10 “(iii) disseminating information to
11 health care providers through professional
12 societies about any serious risks of the
13 drug and any protocol to assure safe use.

14 “(D) PREREVIEW.—

15 “(i) IN GENERAL.—If the Secretary
16 determines that prereview of advertise-
17 ments is necessary to ensure the inclusion
18 of a true statement in such advertisements
19 of information in brief summary relating to
20 a serious risk listed in the labeling of a
21 drug, or relating to a protocol to ensure
22 the safe use described in the labeling of the
23 drug, the risk evaluation and mitigation
24 strategy for the drug may require that the
25 applicant submit to the Secretary adver-

1 tisements of the drug for prereview not
2 later than 45 days before dissemination of
3 the advertisement

4 “(ii) SPECIFICATION OF ADVERTISE-
5 MENTS.—The Secretary may specify the
6 advertisements required to be submitted
7 under clause (i).

8 “(E) SPECIFIC DISCLOSURES.—

9 “(i) SERIOUS RISK; SAFETY PRO-
10 TOCOL.—If the Secretary determines that
11 advertisements lacking a specific disclosure
12 about a serious risk listed in the labeling
13 of a drug or about a protocol to ensure
14 safe use described in the labeling of the
15 drug would be false or misleading, the risk
16 evaluation and mitigation strategy for the
17 drug may require that the applicant in-
18 clude in advertisements of the drug such
19 disclosure.

20 “(ii) DATE OF APPROVAL.—If the
21 Secretary determines that advertisements
22 lacking a specific disclosure of the date a
23 drug was approved and disclosure of a se-
24 rious risk would be false or misleading, the
25 risk evaluation and mitigation strategy for

1 the drug may require that the applicant in-
2 clude in advertisements of the drug such
3 disclosure.

4 “(iii) SPECIFICATION OF ADVERTISE-
5 MENTS.—The Secretary may specify the
6 advertisements required to include a spe-
7 cific disclosure under clause (i) or (ii).

8 “(iv) REQUIRED SAFETY SURVEIL-
9 LANCE.—If the approved risk evaluation
10 and mitigation strategy for a drug requires
11 the specific disclosure under clause (ii), the
12 Secretary shall—

13 “(I) consider identifying and as-
14 sessing all serious risks of using the
15 drug to be a priority safety question
16 under subsection (k)(3)(B);

17 “(II) not less frequently than
18 every 3 months, evaluate the reports
19 under subsection (k)(1) and the rou-
20 tine active surveillance as available
21 under subsection (k)(3) with respect
22 to such priority drug safety question
23 to determine whether serious risks
24 that might occur among patients ex-
25 pected to be treated with the drug

1 have been adequately identified and
2 assessed;

3 “(III) remove such specific dis-
4 closure requirement as an element of
5 such strategy if such serious risks
6 have been adequately identified and
7 assessed; and

8 “(IV) consider whether a specific
9 disclosure under clause (i) should be
10 required.

11 “(6) PROVIDING SAFE ACCESS FOR PATIENTS
12 TO DRUGS WITH KNOWN SERIOUS RISKS THAT
13 WOULD OTHERWISE BE UNAVAILABLE.—

14 “(A) ALLOWING SAFE ACCESS TO DRUGS
15 WITH KNOWN SERIOUS RISKS.—The Secretary
16 may require that the risk evaluation and miti-
17 gation strategy for a drug include such ele-
18 ments as are necessary to assure safe use of the
19 drug, because of its inherent toxicity or poten-
20 tial harmfulness, if the Secretary determines
21 that—

22 “(i) the drug, which has been shown
23 to be effective, but is associated with a se-
24 rious adverse drug experience, can be ap-
25 proved only if, or would be withdrawn un-

1 less, such elements are required as part of
2 such strategy to mitigate a specific serious
3 risk listed in the labeling of the drug; and

4 “(ii) for a drug initially approved
5 without elements to assure safe use, other
6 elements under paragraphs (3), (4), and
7 (5) are not sufficient to mitigate such seri-
8 ous risk.

9 “(B) ASSURING ACCESS AND MINIMIZING
10 BURDEN.—Such elements to assure safe use
11 under subparagraph (A) shall—

12 “(i) be commensurate with the spe-
13 cific serious risk listed in the labeling of
14 the drug;

15 “(ii) within 30 days of the date on
16 which any element under subparagraph (A)
17 is imposed, be posted publicly by the Sec-
18 retary with an explanation of how such ele-
19 ments will mitigate the observed safety
20 risk;

21 “(iii) considering such risk, not be un-
22 duly burdensome on patient access to the
23 drug, considering in particular—

1 “(I) patients with serious or life-
2 threatening diseases or conditions;
3 and

4 “(II) patients who have difficulty
5 accessing health care (such as pa-
6 tients in rural or medically under-
7 served areas); and

8 “(iv) to the extent practicable, so as
9 to minimize the burden on the health care
10 delivery system—

11 “(I) conform with elements to as-
12 sure safe use for other drugs with
13 similar, serious risks; and

14 “(II) be designed to be compat-
15 ible with established distribution, pro-
16 curement, and dispensing systems for
17 drugs.

18 “(C) ELEMENTS TO ASSURE SAFE USE.—

19 The elements to assure safe use under subpara-
20 graph (A) shall include 1 or more goals to miti-
21 gate a specific serious risk listed in the labeling
22 of the drug and, to mitigate such risk, may re-
23 quire that—

24 “(i) health care providers who pre-
25 scribe the drug have particular training or

1 experience, or are specially certified (which
2 training or certification with respect to the
3 drug shall be available to any willing pro-
4 vider from a frontier area in a widely avail-
5 able training or certification method (in-
6 cluding an on-line course or via mail) as
7 approved by the Secretary at minimal cost
8 to the provider);

9 “(ii) pharmacies, practitioners, or
10 health care settings that dispense the drug
11 are specially certified (which certification
12 shall be available to any willing provider
13 from a frontier area);

14 “(iii) the drug be dispensed to pa-
15 tients only in certain health care settings,
16 such as hospitals;

17 “(iv) the drug be dispensed to pa-
18 tients with evidence or other documenta-
19 tion of safe-use conditions, such as labora-
20 tory test results;

21 “(v) each patient using the drug be
22 subject to certain monitoring; or

23 “(vi) each patient using the drug be
24 enrolled in a registry.

1 “(D) IMPLEMENTATION SYSTEM.—The ele-
2 ments to assure safe use under subparagraph
3 (A) that are described in clauses (ii), (iii), or
4 (iv) of subparagraph (C) may include a system
5 through which the applicant is able to take rea-
6 sonable steps to—

7 “(i) monitor and evaluate implementa-
8 tion of such elements by health care pro-
9 viders, pharmacists, and other parties in
10 the health care system who are responsible
11 for implementing such elements; and

12 “(ii) work to improve implementation
13 of such elements by such persons.

14 “(E) EVALUATION OF ELEMENTS TO AS-
15 SURE SAFE USE.—The Secretary, through the
16 Drug Safety and Risk Management Advisory
17 Committee (or successor committee) of the
18 Food and Drug Administration, shall—

19 “(i) seek input from patients, physi-
20 cians, pharmacists, and other health care
21 providers about how elements to assure
22 safe use under this paragraph for 1 or
23 more drugs may be standardized so as not
24 to be—

1 “(I) unduly burdensome on pa-
2 tient access to the drug; and

3 “(II) to the extent practicable,
4 minimize the burden on the health
5 care delivery system;

6 “(ii) at least annually, evaluate, for 1
7 or more drugs, the elements to assure safe
8 use of such drug to assess whether the ele-
9 ments—

10 “(I) assure safe use of the drug;

11 “(II) are not unduly burdensome
12 on patient access to the drug; and

13 “(III) to the extent practicable,
14 minimize the burden on the health
15 care delivery system; and

16 “(iii) considering such input and eval-
17 uations—

18 “(I) issue or modify agency guid-
19 ance about how to implement the re-
20 quirements of this paragraph; and

21 “(II) modify elements under this
22 paragraph for 1 or more drugs as ap-
23 propriate.

24 “(F) ADDITIONAL MECHANISMS TO AS-
25 SURE ACCESS.—The mechanisms under section

1 561 to provide for expanded access for patients
2 with serious or life-threatening diseases or con-
3 ditions may be used to provide access for pa-
4 tients with a serious or life-threatening disease
5 or condition, the treatment of which is not an
6 approved use for the drug, to a drug that is
7 subject to elements to assure safe use under
8 this paragraph. The Secretary shall promulgate
9 regulations for how a physician may provide the
10 drug under the mechanisms of section 561.

11 “(G) WAIVER IN PUBLIC HEALTH EMER-
12 GENCIES.—The Secretary may waive any re-
13 quirement of this paragraph during the period
14 described in section 319(a) of the Public Health
15 Service Act with respect to a qualified counter-
16 measure described under section 319F–1(a)(2)
17 of such Act, to which a requirement under this
18 paragraph has been applied, if the Secretary
19 has—

20 “(i) declared a public health emer-
21 gency under such section 319; and

22 “(ii) determined that such waiver is
23 required to mitigate the effects of, or re-
24 duce the severity of, such public health
25 emergency.

1 “(7) SUBMISSION AND REVIEW OF RISK EVAL-
2 UATION AND MITIGATION STRATEGY.—

3 “(A) PROPOSED RISK EVALUATION AND
4 MITIGATION STRATEGY.—

5 “(i) VOLUNTARY PROPOSAL.—If there
6 is a signal of a serious risk with a drug,
7 an applicant may include a proposed risk
8 evaluation and mitigation strategy for the
9 drug in an application, including in a sup-
10 plemental application, for the drug under
11 subsection (b) or section 351 of the Public
12 Health Service Act.

13 “(ii) REQUIRED PROPOSAL.—

14 “(I) DETERMINATION NEC-
15 CESSARY TO REQUIRE A PROPOSAL.—

16 “(aa) IN GENERAL.—The
17 Secretary may require that the
18 applicant for a drug submit a
19 proposed risk evaluation and
20 mitigation strategy for a drug if
21 the Secretary (acting through the
22 office responsible for reviewing
23 the drug and the office respon-
24 sible for postapproval safety with
25 respect to the drug) determines

1 that, based on a signal of a seri-
2 ous risk with the drug, a risk
3 evaluation and mitigation strat-
4 egy is necessary to assess such
5 signal or mitigate such serious
6 risk.

7 “(bb) NON-DELEGATION.—A
8 determination under item (aa)
9 for a drug shall be made by indi-
10 viduals at or above the level of
11 individuals empowered to approve
12 a drug (such as division directors
13 within the Center for Drug Eval-
14 uation and Research).

15 “(II) CIRCUMSTANCES IN WHICH
16 A PROPOSAL MAY BE REQUIRED.—
17 The applicant shall submit a proposed
18 risk evaluation and mitigation strat-
19 egy for a drug—

20 “(aa) in response to a letter
21 from the Secretary (acting
22 through the office responsible for
23 reviewing the drug and the office
24 responsible for postapproval safe-
25 ty with respect to the drug) sent

1 regarding an application, includ-
2 ing a supplemental application,
3 for the drug, if the Secretary de-
4 termines that data or information
5 in the application indicates that
6 an element under paragraph (4),
7 (5), or (6) should be included in
8 a strategy for the drug;

9 “(bb) within a timeframe
10 specified by the Secretary, not to
11 be less than 45 days, when or-
12 dered by the Secretary (acting
13 through such offices), if the Sec-
14 retary determines that new safety
15 information indicates that—

16 “(AA) the labeling of
17 the drug should be changed;
18 or

19 “(BB) an element
20 under paragraph (4) or (5)
21 should be included in a
22 strategy for the drug; or

23 “(cc) within 90 days when
24 ordered by the Secretary (acting
25 through such offices), if the Sec-

1 retary determines that new safety
2 information indicates that an ele-
3 ment under paragraph (6) should
4 be included in a strategy for the
5 drug.

6 “(iii) CONTENT OF LETTER.—A letter
7 under clause (ii)(II)(aa) shall describe—

8 “(I) the data or information in
9 the application that warrants the pro-
10 posal of a risk evaluation and mitiga-
11 tion strategy for the drug; and

12 “(II) what elements under para-
13 graphs (4), (5), or (6) should be in-
14 cluded in a strategy for the drug.

15 “(iv) CONTENT OF ORDER.—An order
16 under item (aa) or (bb) of clause (ii)(II)
17 shall describe—

18 “(I) the new safety information
19 with respect to the drug that warrants
20 the proposal of a risk evaluation and
21 mitigation strategy for the drug; and

22 “(II) whether and how the label-
23 ing of the drug should be changed and
24 what elements under paragraphs (4),

1 (5), or (6) should be included in a
2 strategy for the drug.

3 “(v) CONTENT OF PROPOSAL.—A pro-
4 posed risk evaluation and mitigation strat-
5 egy—

6 “(I) shall include a timetable as
7 described under paragraph (3)(B);
8 and

9 “(II) may also include additional
10 elements as provided for under para-
11 graphs (4), (5), and (6).

12 “(B) ASSESSMENT AND MODIFICATION OF
13 A RISK EVALUATION AND MITIGATION STRAT-
14 EGY.—

15 “(i) VOLUNTARY ASSESSMENTS.—If a
16 risk evaluation and mitigation strategy for
17 a drug is required, the applicant may sub-
18 mit to the Secretary an assessment of, and
19 propose a modification to, such approved
20 strategy for the drug at any time.

21 “(ii) REQUIRED ASSESSMENTS.—If a
22 risk evaluation and mitigation strategy for
23 a drug is required, the applicant shall sub-
24 mit an assessment of, and may propose a

1 modification to, such approved strategy for
2 the drug—

3 “(I) when submitting an applica-
4 tion, including a supplemental appli-
5 cation, for a new indication under
6 subsection (b) or section 351 of the
7 Public Health Service Act;

8 “(II) when required by the strat-
9 egy, as provided for in the timetable
10 under paragraph (3)(B);

11 “(III) within a timeframe speci-
12 fied by the Secretary, not to be less
13 than 45 days, when ordered by the
14 Secretary (acting through the offices
15 described in subparagraph (A)(ii)(I)),
16 if the Secretary determines that new
17 safety information indicates that an
18 element under paragraph (3) or (4)
19 should be modified or added to the
20 strategy;

21 “(IV) within 90 days when or-
22 dered by the Secretary (acting
23 through such offices), if the Secretary
24 determines that new safety informa-
25 tion indicates that an element under

1 paragraph (6) should be modified or
2 added to the strategy; or

3 “(V) within 15 days when or-
4 dered by the Secretary (acting
5 through such offices), if the Secretary
6 determines that there may be a cause
7 for action by the Secretary under sub-
8 section (e).

9 “(iii) CONTENT OF ORDER.—An order
10 under subclauses (III), (IV), or (V) of
11 clause (ii) shall describe—

12 “(I) the new safety information
13 with respect to the drug that warrants
14 an assessment of the approved risk
15 evaluation and mitigation strategy for
16 the drug; and

17 “(II) whether and how such
18 strategy should be modified because of
19 such information.

20 “(iv) ASSESSMENT.—An assessment
21 of the approved risk evaluation and mitiga-
22 tion strategy for a drug shall include—

23 “(I) a description of new safety
24 information, if any, with respect to
25 the drug;

1 “(II) whether and how to modify
2 such strategy because of such infor-
3 mation;

4 “(III) with respect to any post-
5 approval study required under para-
6 graph (4)(B) or otherwise undertaken
7 by the applicant to investigate a safe-
8 ty issue, the status of such study, in-
9 cluding whether any difficulties com-
10 pleting the study have been encoun-
11 tered;

12 “(IV) with respect to any post-
13 approval clinical trial required under
14 paragraph (4)(C) or otherwise under-
15 taken by the applicant to investigate a
16 safety issue, the status of such clinical
17 trial, including whether enrollment
18 has begun, the number of participants
19 enrolled, the expected completion date,
20 whether any difficulties completing
21 the clinical trial have been encoun-
22 tered, and registration information
23 with respect to requirements under
24 subsections (i) and (j) of section 402
25 of the Public Health Service Act; and

1 “(V) with respect to any goal
2 under paragraph (6) and considering
3 input and evaluations, if applicable,
4 under paragraph (6)(E), an assess-
5 ment of how well the elements to as-
6 sure safe use are meeting the goal of
7 increasing safe access to drugs with
8 known serious risks or whether the
9 goal or such elements should be modi-
10 fied.

11 “(v) MODIFICATION.—A modification
12 (whether an enhancement or a reduction)
13 to the approved risk evaluation and mitiga-
14 tion strategy for a drug may include the
15 addition or modification of any element
16 under subparagraph (A) or (B) of para-
17 graph (3) or the addition, modification, or
18 removal of any element under paragraph
19 (4), (5), or (6), such as—

20 “(I) a labeling change, including
21 the addition of a boxed warning;

22 “(II) adding a postapproval
23 study or clinical trial requirement;

24 “(III) modifying a postapproval
25 study or clinical trial requirement

1 (such as a change in trial design due
2 to legitimate difficulties recruiting
3 participants);

4 “(IV) adding, modifying, or re-
5 moving an element on advertising
6 under subparagraph (D), (E), or (F)
7 of paragraph (5);

8 “(V) adding, modifying, or re-
9 moving an element to assure safe use
10 under paragraph (6); or

11 “(VI) modifying the timetable for
12 assessments of the strategy under
13 paragraph (3)(B), including to elimi-
14 nate assessments.

15 “(C) REVIEW.—The Secretary (acting
16 through the offices described in subparagraph
17 (A)(ii)(I)) shall promptly review the proposed
18 risk evaluation and mitigation strategy for a
19 drug submitted under subparagraph (A), or an
20 assessment of the approved risk evaluation and
21 mitigation strategy for a drug submitted under
22 subparagraph (B).

23 “(D) DISCUSSION.—The Secretary (acting
24 through the offices described in subparagraph
25 (A)(ii)(I)) shall initiate discussions of the pro-

1 posed risk evaluation and mitigation strategy
2 for a drug submitted under subparagraph (A),
3 or of an assessment of the approved risk eval-
4 uation and mitigation strategy for a drug sub-
5 mitted under subparagraph (B), with the appli-
6 cant to determine a strategy—

7 “(i) if the proposed strategy or assess-
8 ment is submitted as part of an application
9 (including a supplemental application)
10 under subparagraph (A)(i), (A)(ii)(II)(aa),
11 or (B)(ii)(I), by the target date for com-
12 munication of feedback from the review
13 team to the applicant regarding proposed
14 labeling and postmarketing study commit-
15 ments, as set forth in the letters described
16 in section 735(a);

17 “(ii) if the proposed strategy is sub-
18 mitted under subparagraph (A)(ii)(II)(bb)
19 or the assessment is submitted under sub-
20 clause (II) or (III) of subparagraph
21 (B)(ii), not later than 20 days after such
22 submission;

23 “(iii) if the proposed strategy is sub-
24 mitted under subparagraph (A)(ii)(II)(cc)
25 or the assessment is submitted under sub-

1 paragraph (B)(i) or under subparagraph
2 (B)(ii)(IV), not later than 30 days after
3 such submission; or

4 “(iv) if the assessment is submitted
5 under subparagraph (B)(ii)(V), not later
6 than 10 days after such submission.

7 “(E) ACTION.—

8 “(i) IN GENERAL.—Unless the appli-
9 cant requests the dispute resolution proc-
10 ess as described under subparagraph (F)
11 or (G), the Secretary (acting through the
12 offices described in subparagraph
13 (A)(ii)(I)) shall approve and include the
14 risk evaluation and mitigation strategy for
15 a drug, or any modification to the strategy
16 (including a timeframe for implementing
17 such modification), with—

18 “(I) the action letter on the ap-
19 plication, if a proposed strategy is
20 submitted under subparagraph (A)(i)
21 or (A)(ii)(II)(aa) or an assessment of
22 the strategy is submitted under sub-
23 paragraph (B)(ii)(I); or

24 “(II) an order, which shall be
25 made public, issued not later than 50

1 days after the date discussions of such
2 proposed strategy or modification
3 begin under subparagraph (D), if a
4 proposed strategy is submitted under
5 item (bb) or (cc) of subparagraph
6 (A)(ii)(II) or an assessment of the
7 strategy is submitted under subpara-
8 graph (B)(i) or under subclause (II),
9 (III), (IV), or (V) of subparagraph
10 (B)(ii).

11 “(ii) INACTION.—An approved risk
12 evaluation and mitigation strategy shall re-
13 main in effect until the Secretary acts, if
14 the Secretary fails to act as provided under
15 clause (i).

16 “(F) DISPUTE RESOLUTION AT INITIAL
17 APPROVAL.—If a proposed risk evaluation and
18 mitigation strategy is submitted under subpara-
19 graph (A)(i) or (A)(ii)(II)(aa) in an application
20 for initial approval of a drug and there is a dis-
21 pute about the strategy, the applicant shall use
22 the major dispute resolution procedures as set
23 forth in the letters described in section 735(a).

24 “(G) DISPUTE RESOLUTION IN ALL OTHER
25 CASES.—

1 “(i) REQUEST FOR REVIEW.—In any
2 case other than a submission under sub-
3 paragraph (A)(i) or (A)(ii)(II)(aa) in an
4 application for initial approval of a drug if
5 there is a dispute about the strategy, not
6 earlier than 15 days, and not later than 35
7 days, after discussions under subparagraph
8 (D) have begun, the applicant shall request
9 in writing that the dispute be reviewed by
10 the Drug Safety Oversight Board.

11 “(ii) SCHEDULING REVIEW.—If the
12 applicant requests review under clause (i),
13 the Secretary—

14 “(I)(aa) shall schedule the dis-
15 pute for review at 1 of the next 2 reg-
16 ular meetings of the Drug Safety
17 Oversight Board, whichever meeting
18 date is more practicable; or

19 “(bb) may convene a special
20 meeting of the Drug Safety Oversight
21 Board to review the matter more
22 promptly, including to meet an action
23 deadline on an application (including
24 a supplemental application);

1 “(II) shall give advance notice to
2 the public through the Federal Reg-
3 ister and on the Internet website of
4 the Food and Drug Administration—

5 “(aa) that the drug is to be
6 discussed by the Drug Safety
7 Oversight Board; and

8 “(bb) of the date on which
9 the Drug Safety Oversight Board
10 shall discuss such drug; and

11 “(III) shall apply section 301(j),
12 section 552 of title 5, and section
13 1905 of title 18, United States Code,
14 to any request for information about
15 such review.

16 “(iii) AGREEMENT AFTER DISCUSSION
17 OR ADMINISTRATIVE APPEALS.—

18 “(I) FURTHER DISCUSSION OR
19 ADMINISTRATIVE APPEALS.—A re-
20 quest for review under clause (i) shall
21 not preclude—

22 “(aa) further discussions to
23 reach agreement on the risk eval-
24 uation and mitigation strategy;
25 or

“(bb) the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including the major dispute resolution procedures as set forth in the letters described in section 735(a).

“(II) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (vi), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) and the applicant may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

“(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight

1 Board described in clause (ii), the Board
2 shall—

3 “(I) hear from both parties; and

4 “(II) review the dispute.

5 “(v) RECOMMENDATION OF THE
6 BOARD.—Not later than 5 days after such
7 meeting of the Drug Safety Oversight
8 Board, the Board shall provide a written
9 recommendation on resolving the dispute
10 to the Secretary.

11 “(vi) ACTION BY THE SECRETARY.—

12 “(I) ACTION LETTER.—With re-
13 spect to a proposed risk evaluation
14 and mitigation strategy submitted
15 under subparagraph (A)(i) or
16 (A)(ii)(II)(aa) or to an assessment of
17 the strategy submitted under subpara-
18 graph (B)(ii)(I), the Secretary shall
19 issue an action letter that resolves the
20 dispute not later than the later of—

21 “(aa) the action deadline for
22 the action letter on the applica-
23 tion; or

1 “(bb) 7 days after receiving
2 the recommendation of the Drug
3 Safety Oversight Board.

4 “(II) ORDER.—With respect to a
5 proposed risk evaluation and mitiga-
6 tion strategy submitted under item
7 (bb) or (cc) of subparagraph
8 (A)(ii)(II) or an assessment of the
9 risk evaluation and mitigation strat-
10 egy under subparagraph (B)(i) or
11 under subclause (II), (III), (IV), or
12 (V) of subparagraph (B)(ii), the Sec-
13 retary shall issue an order, which
14 (with the recommendation of the
15 Drug Safety Oversight Board) shall
16 be made public, that resolves the dis-
17 pute not later than 7 days after re-
18 ceiving the recommendation of the
19 Drug Safety Oversight Board.

20 “(vii) INACTION.—An approved risk
21 evaluation and mitigation strategy shall re-
22 main in effect until the Secretary acts, if
23 the Secretary fails to act as provided for
24 under clause (vi).

“(viii) EFFECT ON ACTION DEAD-
LINE.—With respect to the application or
supplemental application in which a pro-
posed risk evaluation and mitigation strat-
egy is submitted under subparagraph
(A)(i) or (A)(ii)(II)(aa) or in which an as-
sessment of the strategy is submitted
under subparagraph (B)(ii)(I), the Sec-
retary shall be considered to have met the
action deadline for the action letter on
such application if the applicant requests
the dispute resolution process described in
this subparagraph and if the Secretary—

“(I) has initiated the discussions
described under subparagraph (D) by
the target date referred to in subpara-
graph (D)(i); and

“(II) has complied with the tim-
ing requirements of scheduling review
by the Drug Safety Oversight Board,
providing a written recommendation,
and issuing an action letter under
clauses (ii), (v), and (vi), respectively.

“(ix) DISQUALIFICATION.—No indi-
vidual who is an employee of the Food and

1 Drug Administration and who reviews a
2 drug or who participated in an administra-
3 tive appeal under clause (iii)(I) with re-
4 spect to such drug may serve on the Drug
5 Safety Oversight Board at a meeting under
6 clause (iv) to review a dispute about the
7 risk evaluation and mitigation strategy for
8 such drug.

9 “(x) ADDITIONAL EXPERTISE.—The
10 Drug Safety Oversight Board may add
11 members with relevant expertise from the
12 Food and Drug Administration, including
13 the Office of Pediatrics, the Office of
14 Women’s Health, or the Office of Rare
15 Diseases, or from other Federal public
16 health or health care agencies, for a meet-
17 ing under clause (iv) of the Drug Safety
18 Oversight Board.

19 “(H) USE OF ADVISORY COMMITTEES.—
20 The Secretary (acting through the offices de-
21 scribed in subparagraph (A)(ii)(I)) may convene
22 a meeting of 1 or more advisory committees of
23 the Food and Drug Administration to—

24 “(i) review a concern about the safety
25 of a drug or class of drugs, including be-

1 fore an assessment of the risk evaluation
2 and mitigation strategy or strategies of
3 such drug or drugs is required to be sub-
4 mitted under subclause (II), (III), (IV), or
5 (V) of subparagraph (B)(ii);

6 “(ii) review the risk evaluation and
7 mitigation strategy or strategies of a drug
8 or group of drugs; or

9 “(iii) with the consent of the appli-
10 cant, review a dispute under subparagraph
11 (G).

12 “(I) PROCESS FOR ADDRESSING DRUG
13 CLASS EFFECTS.—

14 “(i) IN GENERAL.—When a concern
15 about a serious risk of a drug may be re-
16 lated to the pharmacological class of the
17 drug, the Secretary (acting through the of-
18 fices described in subparagraph (A)(ii)(I))
19 may defer assessments of the approved
20 risk evaluation and mitigation strategies
21 for such drugs until the Secretary has—

22 “(I) convened, after appropriate
23 public notice, 1 or more public meet-
24 ings to consider possible responses to
25 such concern; or

1 “(II) gathered additional infor-
2 mation or data about such concern.

3 “(ii) PUBLIC MEETINGS.—Such public
4 meetings may include—

5 “(I) 1 or more meetings of the
6 applicants for such drugs;

7 “(II) 1 or more meetings of 1 or
8 more advisory committees of the Food
9 and Drug Administration, as provided
10 for under subparagraph (H); or

11 “(III) 1 or more workshops of
12 scientific experts and other stake-
13 holders.

14 “(iii) ACTION.—After considering the
15 discussions from any meetings under
16 clause (ii), the Secretary may—

17 “(I) announce in the Federal
18 Register a planned regulatory action,
19 including a modification to each risk
20 evaluation and mitigation strategy, for
21 drugs in the pharmacological class;

22 “(II) seek public comment about
23 such action; and

1 “(III) after seeking such com-
2 ment, issue an order addressing such
3 regulatory action.

4 “(J) INTERNATIONAL COORDINATION.—
5 The Secretary (acting through the offices de-
6 scribed in subparagraph (A)(ii)(I)) may coordi-
7 nate the timetable for submission of assess-
8 ments under paragraph (3)(B), a study under
9 paragraph (4)(B), or a clinical trial under para-
10 graph (4)(C), with efforts to identify and assess
11 the serious risks of such drug by the marketing
12 authorities of other countries whose drug ap-
13 proval and risk management processes the Sec-
14 retary deems comparable to the drug approval
15 and risk management processes of the United
16 States.

17 “(K) EFFECT.—Use of the processes de-
18 scribed in subparagraphs (I) and (J) shall not
19 delay action on an application or a supplement
20 to an application for a drug.

21 “(L) NO EFFECT ON LABELING CHANGES
22 THAT DO NOT REQUIRE PREAPPROVAL.—In the
23 case of a labeling change to which section
24 314.70 of title 21, Code of Federal Regulations
25 (or any successor regulation), applies for which

1 the submission of a supplemental application is
2 not required or for which distribution of the
3 drug involved may commence upon the receipt
4 by the Secretary of a supplemental application
5 for the change, the submission of an assessment
6 of the approved risk evaluation and mitigation
7 strategy for the drug under this subsection is
8 not required.

9 “(8) DRUG SAFETY OVERSIGHT BOARD.—

10 “(A) IN GENERAL.—There is established a
11 Drug Safety Oversight Board.

12 “(B) COMPOSITION; MEETINGS.—The
13 Drug Safety Oversight Board shall—

14 “(i) be composed of scientists and
15 health care practitioners appointed by the
16 Secretary, each of whom is an employee of
17 the Federal Government;

18 “(ii) include representatives from of-
19 fices throughout the Food and Drug Ad-
20 ministration (including the offices respon-
21 sible for postapproval safety of drugs);

22 “(iii) include at least 1 representative
23 each from the National Institutes of
24 Health, the Department of Health and
25 Human Services (other than the Food and

1 Drug Administration), and the Veterans
2 Health Administration; and

3 “(iv) meet at least monthly to provide
4 oversight and advice to the Secretary on
5 the management of important drug safety
6 issues.

7 “(9) CIVIL MONETARY PENALTY.—Notwith-
8 standing any other provision of this Act, an appli-
9 cant (as such term is defined for purposes of this
10 section) that knowingly fails to comply with a re-
11 quirement of an approved risk evaluation and miti-
12 gation strategy under this subsection shall be subject
13 to a civil money penalty of \$250,000 for the first
14 30-day period that the applicant is in noncompli-
15 ance, and such amount shall double for every 30-day
16 period thereafter that the requirement is not com-
17 plied with, not to exceed \$2,000,000.”.

18 **SEC. 203. ENFORCEMENT.**

19 (a) MISBRANDING.—Section 502 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
21 ed by adding at the end the following:

22 “(x) If it is a drug subject to an approved risk evalua-
23 tion and mitigation strategy under section 505(o) and the
24 applicant for such drug fails to—

1 “(1) make a labeling change required by such
2 strategy after the Secretary has approved such strat-
3 egy or completed review of, and acted on, an assess-
4 ment of such strategy under paragraph (7) of such
5 section; or

6 “(2) comply with a requirement of such strat-
7 egy with respect to advertising as provided for under
8 subparagraph (D), (E), or (F) of paragraph (5) of
9 such section.”.

10 (b) CIVIL PENALTIES.—Section 303(f) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is
12 amended—

13 (1) by redesignating paragraphs (3), (4), and
14 (5) as paragraphs (4), (5), and (6), respectively;

15 (2) by inserting after paragraph (2) the fol-
16 lowing:

17 “(3) An applicant (as such term is used in sec-
18 tion 505(o)) who knowingly fails to comply with a
19 requirement of an approved risk evaluation and miti-
20 gation strategy under such section 505(o) shall be
21 subject to a civil money penalty of not less than
22 \$15,000 and not more than \$250,000 per violation,
23 and not to exceed \$1,000,000 for all such violations
24 adjudicated in a single proceeding.”;

1 (3) in paragraph (2)(C), by striking “paragraph
2 (3)(A)” and inserting “paragraph (4)(A)”;

3 (4) in paragraph (4), as so redesignated, by
4 striking “paragraph (1) or (2)” each place it ap-
5 pears and inserting “paragraph (1), (2), or (3)”;
6 and

7 (5) in paragraph (6), as so redesignated, by
8 striking “paragraph (4)” each place it appears and
9 inserting “paragraph (5)”.

10 **SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL**
11 **PRODUCTS.**

12 Section 351 of the Public Health Service Act (42
13 U.S.C. 262) is amended—

14 (1) in subsection (a)(2), by adding at the end
15 the following:

16 “(D) RISK EVALUATION AND MITIGATION STRAT-
17 EGY.—A person that submits an application for a license
18 for a drug under this paragraph may submit to the Sec-
19 retary as part of the application a proposed risk evaluation
20 and mitigation strategy as described under section 505(o)
21 of the Federal Food, Drug, and Cosmetic Act.”; and

22 (2) in subsection (j), by inserting “, including
23 the requirements under section 505(o) of such Act,”
24 after “, and Cosmetic Act”.

1 **SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
2 **APPROVAL.**

3 Section 505(e) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355(e)) is amended by adding at
5 the end the following: “The Secretary may withdraw the
6 approval of an application submitted under this section,
7 or suspend the approval of such an application, as pro-
8 vided under this subsection, without first ordering the ap-
9 plicant to submit an assessment of the approved risk eval-
10 uation and mitigation strategy for the drug under sub-
11 section (o)(7)(B)(ii)(V).”.

12 **SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG**
13 **APPLICATION.**

14 Section 505(j)(2) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding
16 at the end the following:

17 “(E) RISK EVALUATION AND MITIGATION STRATEGY
18 REQUIREMENT.—

19 “(i) IN GENERAL.—A drug that is the subject
20 of an abbreviated new drug application under this
21 subsection shall be subject to only the following ele-
22 ments of the approved risk evaluation and mitigation
23 strategy if required under subsection (o) for the ap-
24 plicable listed drug:

25 “(I) Labeling, as required under subsection
26 (o)(3)(A) for the applicable listed drug.

1 “(II) A Medication Guide or patient pack-
2 age insert, if required under subsection
3 (o)(5)(B) for the applicable listed drug.

4 “(III) Prereview of advertising, if required
5 under subsection (o)(5)(D) for the applicable
6 listed drug.

7 “(IV) Specific disclosures in advertising, if
8 required under subsection (o)(5)(E) for the ap-
9 plicable listed drug.

10 “(V) Elements to assure safe use, if re-
11 quired under subsection (o)(6) for the applica-
12 ble listed drug, except that such drug may use
13 a different, comparable aspect of such elements
14 as are necessary to assure safe use of such drug
15 if—

16 “(aa) the corresponding aspect of the
17 elements to assure safe use for the applica-
18 ble listed drug is claimed by a patent that
19 has not expired or is a method or process
20 that as a trade secret is entitled to protec-
21 tion; and

22 “(bb) the applicant certifies that it
23 has sought a license for use of such aspect
24 of the elements to assure safe use for the
25 applicable listed drug.

1 “(ii) ACTION BY SECRETARY.—For an applica-
2 ble listed drug for which a drug is approved under
3 this subsection, the Secretary—

4 “(I) shall undertake any communication
5 plan to health care providers required under
6 section (o)(5)(C) for the applicable listed drug;

7 “(II) shall conduct, or contract for, any
8 postapproval study required under subsection
9 (o)(4)(B) for the applicable listed drug;

10 “(III) shall inform the applicant for a drug
11 approved under this subsection if the approved
12 risk evaluation and mitigation strategy for the
13 applicable listed drug is modified; and

14 “(IV) in order to minimize the burden on
15 the health care delivery system of different ele-
16 ments to assure safe use for the drug approved
17 under this subsection and the applicable listed
18 drug, may seek to negotiate a voluntary agree-
19 ment with the owner of the patent, method, or
20 process for a license under which the applicant
21 for such drug may use an aspect of the ele-
22 ments to assure safe use, if required under sub-
23 section (o)(6) for the applicable listed drug,
24 that is claimed by a patent that has not expired

1 or is a method or process that as a trade secret
2 is entitled to protection.”.

3 **SEC. 207. RESOURCES.**

4 (a) **USER FEES.**—Subparagraph (F) of section
5 735(d)(6) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 379g(d)(6)), as amended by section 103, is
7 amended—

8 (1) in clause (ii), by striking “systems); and”
9 and inserting “systems);”

10 (2) in clause (iii), by striking “bases).” and in-
11 serting “bases); and”; and

12 (3) by adding at the end the following:

13 “(iv) reviewing, implementing, and en-
14 suring compliance with risk evaluation and
15 mitigation strategies.”.

16 (b) **ADDITIONAL FEE REVENUES FOR DRUG SAFE-**
17 **TY.**—Section 736 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 379h), as amended by section 103,
19 is amended by—

20 (1) striking the subsection designation and all
21 that follows through “.—Except” and inserting the
22 following:

23 “(b) **FEE REVENUE AMOUNTS.**—

24 “(1) **IN GENERAL.**—Except”; and

25 (2) adding at the end the following:

1 “(2) ADDITIONAL FEE REVENUES FOR DRUG
2 SAFETY.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (C), in each of fiscal years 2008 through
5 2012, paragraph (1) shall be applied by sub-
6 stituting the amount determined under sub-
7 paragraph (B) for ‘\$392,783,000’.

8 “(B) AMOUNT DETERMINED.—For any fis-
9 cal year 2008 through 2012, the amount deter-
10 mined under this subparagraph is the sum of—

11 “(i) \$392,783,000; plus

12 “(ii) the amount equal to—

13 “(I)(aa) for fiscal year 2008,
14 \$25,000,000;

15 “(bb) for fiscal year 2009,
16 \$35,000,000;

17 “(cc) for fiscal year 2010,
18 \$45,000,000;

19 “(dd) for fiscal year 2011,
20 \$55,000,000; and

21 “(ee) for fiscal year 2012,
22 \$65,000,000; minus

23 “(II) the amount equal to one-fifth of
24 the excess amount in item (bb), provided
25 that—

1 “(aa) the amount of the total ap-
2 propriation for the Food and Drug
3 Administration for such fiscal year
4 (excluding the amount of fees appro-
5 priated for such fiscal year) exceeds
6 the amount of the total appropriation
7 for the Food and Drug Administra-
8 tion for fiscal year 2007 (excluding
9 the amount of fees appropriated for
10 such fiscal year), adjusted as provided
11 under subsection (c)(1); and

12 “(bb) the amount of the total ap-
13 propriations for the process of human
14 drug review at the Food and Drug
15 Administration for such fiscal year
16 (excluding the amount of fees appro-
17 priated for such fiscal year) exceeds
18 the amount of appropriations for the
19 process of human drug review at the
20 Food and Drug Administration for
21 fiscal year 2007 (excluding the
22 amount of fees appropriated for such
23 fiscal year), adjusted as provided
24 under subsection (c)(1).

1 In making the adjustment under subclause
2 (II) for any fiscal year 2008 through 2012,
3 subsection (c)(1) shall be applied by sub-
4 stituting ‘2007’ for ‘2008.’

5 “(C) LIMITATION.—This paragraph shall
6 not apply for any fiscal year if the amount de-
7 scribed under subparagraph (B)(ii) is less than
8 0.”.

9 (c) STRATEGIC PLAN FOR INFORMATION TECH-
10 NOLOGY.—Not later than 1 year after the date of enact-
11 ment of this title, the Secretary of Health and Human
12 Services (referred to in this title as the “Secretary”) shall
13 submit to the Committee on Health, Education, Labor,
14 and Pensions and the Committee on Appropriations of the
15 Senate and the Committee on Energy and Commerce and
16 the Committee on Appropriations of the House of Rep-
17 resentatives, a strategic plan on information technology
18 that includes—

19 (1) an assessment of the information technology
20 infrastructure, including systems for data collection,
21 access to data in external health care databases,
22 data mining capabilities, personnel, and personnel
23 training programs, needed by the Food and Drug
24 Administration to—

1 (A) comply with the requirements of this
2 subtitle (and the amendments made by this
3 subtitle);

4 (B) achieve interoperability within and
5 among the centers of the Food and Drug Ad-
6 ministration and between the Food and Drug
7 Administration and product application spon-
8 sors;

9 (C) utilize electronic health records;

10 (D) implement routine active surveillance
11 under section 505(k)(3) (including complemen-
12 tary approaches under subsection (c) of such
13 section) of the Federal Food, Drug, and Cos-
14 metic Act, as added by section 201 of this Act;
15 and

16 (E) communicate drug safety information
17 to physicians and other health care providers;

18 (2) an assessment of the extent to which the
19 current information technology assets of the Food
20 and Drug Administration are sufficient to meet the
21 needs assessments under paragraph (1);

22 (3) a plan for enhancing the information tech-
23 nology assets of the Food and Drug Administration
24 toward meeting the needs assessments under para-
25 graph (1); and

1 (4) an assessment of additional resources need-
2 ed to so enhance the information technology assets
3 of the Food and Drug Administration.

4 **SEC. 208. SAFETY LABELING CHANGES.**

5 (a) IN GENERAL.—Subchapter A of chapter V of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
7 et seq.) is amended by inserting after section 506C the
8 following:

9 **“SEC. 506D. SAFETY LABELING CHANGES.**

10 “(a) NEW SAFETY INFORMATION.—

11 “(1) NOTIFICATION.—The holder of an ap-
12 proved application under section 505 of this Act or
13 a license under section 351 of the Public Health
14 Service Act (referred to in this section as a ‘holder’)
15 shall promptly notify the Secretary if the holder be-
16 comes aware of new safety information that the
17 holder believes should be included in the labeling of
18 the drug. The Secretary shall promptly notify the
19 holder if the Secretary becomes aware of new safety
20 information that the Secretary believes should be in-
21 cluded in the labeling of the drug.

22 “(2) DISCUSSION REGARDING LABELING
23 CHANGES.—Following notification pursuant to para-
24 graph (1), the Secretary and holder shall initiate
25 discussions of the new safety information in order to

1 reach agreement on whether the labeling for the
2 drug should be modified to reflect the new safety in-
3 formation and, if so, on the contents of such labeling
4 changes.

5 “(3) SUPPLEMENT.—If the Secretary deter-
6 mines that there is reasonable scientific evidence
7 that an adverse event is associated with use of the
8 drug, the Secretary may request the holder to sub-
9 mit a supplement to an application under section
10 505 of this Act or to a license under section 351 of
11 the Public Health Service Act (referred to in this
12 section as a ‘supplement’) proposing changes to the
13 approved labeling to reflect the new safety informa-
14 tion, including changes to boxed warnings, contra-
15 indications, warnings, precautions, or adverse reac-
16 tions (referred to in this section as a ‘safety labeling
17 change’). If the Secretary determines that no safety
18 labeling change is necessary or appropriate based
19 upon the new safety information, the Secretary shall
20 notify the holder of this determination in writing.

21 “(b) LABELING SUPPLEMENTS.—

22 “(1) IN GENERAL.—The holder shall submit a
23 supplement whenever the holder seeks, either at the
24 holder’s own initiative or at the request of the Sec-
25 retary, to make a safety labeling change.

1 “(2) NONACCELERATED PROCESS.—Unless the
2 accelerated labeling review process described in sub-
3 section (c) is initiated, any supplement proposing a
4 safety labeling change shall be reviewed and acted
5 upon by the Secretary not later than 30 days after
6 the date the Secretary receives the supplement.
7 Until the Secretary acts on such a supplement pro-
8 posing a safety labeling change, the existing ap-
9 proved labeling shall remain in effect and be distrib-
10 uted by the holder without change.

11 “(3) NEW SAFETY INFORMATION.—Nothing in
12 this section shall prohibit the Secretary from inform-
13 ing health care professionals or the public about new
14 safety information prior to approval of a supplement
15 proposing a safety labeling change.

16 “(c) ACCELERATED LABELING REVIEW PROCESS.—
17 An accelerated labeling review process shall be available
18 to resolve disagreements in a timely manner between the
19 Secretary and a holder about the need for, or content of,
20 a safety labeling change, as follows:

21 “(1) REQUEST TO INITIATE ACCELERATED
22 PROCESS.—The accelerated labeling review process
23 shall be initiated upon the written request of either
24 the Secretary or the holder. Such request may be
25 made at any time after the notification described in

1 subsection (a)(1), including during the Secretary's
2 review of a supplement proposing a safety labeling
3 change.

4 “(2) SCIENTIFIC DISCUSSION AND MEETINGS.—

5 “(A) IN GENERAL.—Following initiation of
6 the accelerated labeling review process, the Sec-
7 retary and holder shall immediately initiate dis-
8 cussions to review and assess the new safety in-
9 formation and to reach agreement on whether
10 safety labeling changes are necessary and ap-
11 propriate and, if so, the content of such safety
12 labeling changes.

13 “(B) TIME PERIOD.—The discussions
14 under this paragraph shall not extend for more
15 than 45 calendar days after the initiation of the
16 accelerated labeling review process.

17 “(C) DISPUTE PROCEEDINGS.—If the Sec-
18 retary and holder do not reach an agreement
19 regarding the safety labeling changes by not
20 later than 25 calendar days after the initiation
21 of the accelerated labeling review process, the
22 dispute automatically shall be referred to the
23 director of the drug evaluation office respon-
24 sible for the drug under consideration, who

1 shall be required to take an active role in such
2 discussions.

3 “(3) REQUEST FOR SAFETY LABELING CHANGE
4 AND FAILURE TO AGREE.—If the Secretary and
5 holder fail to reach an agreement on appropriate
6 safety labeling changes by not later than 45 calendar
7 days after the initiation of the accelerated labeling
8 review process—

9 “(A) on the next calendar day (other than
10 a weekend or Federal holiday) after such pe-
11 riod, the Secretary shall—

12 “(i) request in writing that the holder
13 make any safety labeling change that the
14 Secretary determines to be necessary and
15 appropriate based upon the new safety in-
16 formation; or

17 “(ii) notify the holder in writing that
18 the Secretary has determined that no safe-
19 ty labeling change is necessary or appro-
20 priate; and

21 “(B) if the Secretary fails to act within the
22 specified time, or if the holder does not agree
23 to make a safety labeling change requested by
24 the Secretary or does not agree with the Sec-
25 retary’s determination that no labeling change

1 is necessary or appropriate, the Secretary (on
2 his own initiative or upon request by the hold-
3 er) shall refer the matter for expedited review
4 to the Drug Safety Oversight Board.

5 “(4) ACTION BY THE DRUG SAFETY OVERSIGHT
6 BOARD.—Not later than 45 days after receiving a
7 referral under paragraph (3)(B), the Drug Safety
8 Oversight Board shall—

9 “(A) review the new safety information;

10 “(B) review all written material submitted
11 by the Secretary and the holder;

12 “(C) convene a meeting to hear oral pres-
13 entations and arguments from the Secretary
14 and holder; and

15 “(D) make a written recommendation to
16 the Secretary—

17 “(i) concerning appropriate safety la-
18 beling changes, if any; or

19 “(ii) stating that no safety labeling
20 changes are necessary or appropriate based
21 upon the new safety information.

22 “(5) CONSIDERATION OF RECOMMENDA-
23 TIONS.—

24 “(A) ACTION BY THE SECRETARY.—The
25 Secretary shall consider the recommendation of

1 the Drug Safety Oversight Board made under
2 paragraph (4)(D) and, not later than 20 days
3 after receiving the recommendation—

4 “(i) issue an order requiring the hold-
5 er to make any safety labeling change that
6 the Secretary determines to be necessary
7 and appropriate; or

8 “(ii) if the Secretary determines that
9 no safety labeling change is necessary or
10 appropriate, the Secretary shall notify the
11 holder of this determination in writing.

12 “(B) FAILURE TO ACT.—If the Secretary
13 fails to act by not later than 20 days after re-
14 ceiving the recommendation of the Drug Safety
15 Oversight Board, the written recommendation
16 of the Drug Safety Oversight Board shall be
17 considered the order of the Secretary under this
18 paragraph.

19 “(C) NONDELEGATION.—The Secretary’s
20 authority under this paragraph shall not be re-
21 delegated to an individual below the level of the
22 Director of the Center for Drug Evaluation and
23 Research, or the Director of the Center for Bio-
24 logics Evaluation and Research, of the Food
25 and Drug Administration.

“(6) MISBRANDING.—If the holder, not later than 10 days after receiving an order under subparagraph (A) or (B) of paragraph (5), does not agree to make a safety labeling change ordered by the Secretary, the Secretary may deem the drug that is the subject of the request to be misbranded.

7 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed to change the standards in exist-
9 ence on the date of enactment of this section for deter-
10 mining whether safety labeling changes are necessary or
11 appropriate.”.

(b) CONFORMING AMENDMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 et seq.), as amended by section 203, is further amended by adding at the end the following:

16 “(y) If it is a drug and the holder does not agree
17 to make a safety labeling change ordered by the Secretary
18 under section 506D(c) within 10 days after issuance of
19 such an order.”.

20 SEC. 209. POSTMARKET DRUG SAFETY INFORMATION FOR
21 PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic
Act (21 U.S.C. 355), as amended by section 251, is
amended by adding at the end the following:

1 “(r) POSTMARKET DRUG SAFETY INFORMATION FOR
2 PATIENTS AND PROVIDERS.—

3 “(1) ESTABLISHMENT.—Not later than 1 year
4 after the date of enactment of the Enhancing Drug
5 Safety and Innovation Act of 2007, the Secretary
6 shall improve the transparency of pharmaceutical
7 data and allow patients and health care providers
8 better access to pharmaceutical data by developing
9 and maintaining an Internet website that—

10 “(A) provides comprehensive drug safety
11 information for prescription drugs that are ap-
12 proved by the Secretary under this section or li-
13 censed under section 351 of the Public Health
14 Service Act; and

15 “(B) improves communication of drug
16 safety information to patients and providers.

17 “(2) INTERNET WEBSITE.—The Secretary shall
18 carry out paragraph (1) by—

19 “(A) developing and maintaining an acces-
20 sible, consolidated Internet website with easily
21 searchable drug safety information, including
22 the information found on United States Govern-
23 ment Internet websites, such as the United
24 States National Library of Medicine’s Daily
25 Med and Medline Plus websites, in addition to

1 other such websites maintained by the Sec-
2 retary;

3 “(B) ensuring that the information pro-
4 vided on the Internet website is comprehensive
5 and includes, when available and appropriate—

6 “(i) patient labeling and patient pack-
7 aging inserts;

8 “(ii) a link to a list of each drug,
9 whether approved under this section or li-
10 censed under such section 351, for which
11 a Medication Guide, as provided for under
12 part 208 of title 21, Code of Federal Regu-
13 lations (or any successor regulations), is
14 required;

15 “(iii) a link to the clinical trial reg-
16 istry data bank provided for under sub-
17 sections (i) and (j) of section 402 of the
18 Public Health Service Act;

19 “(iv) the most recent safety informa-
20 tion and alerts issued by the Food and
21 Drug Administration for drugs approved
22 by the Secretary under this section, such
23 as product recalls, warning letters, and im-
24 port alerts;

1 “(v) publicly available information
2 about implemented RiskMAPs and risk
3 evaluation and mitigation strategies under
4 subsection (o);

5 “(vi) guidance documents and regula-
6 tions related to drug safety; and

7 “(vii) other material determined ap-
8 propriate by the Secretary;

9 “(C) including links to non-Food and Drug
10 Administration Internet resources that provide
11 access to relevant drug safety information, such
12 as medical journals and studies;

13 “(D) providing access to summaries of the
14 assessed and aggregated data collected from the
15 active surveillance infrastructure under sub-
16 section (k)(3) to provide information of known
17 and serious side-effects for drugs approved by
18 the Secretary under this section or licensed
19 under such section 351;

20 “(E) enabling patients, providers, and
21 drug sponsors to submit adverse event reports
22 through the Internet website;

23 “(F) providing educational materials for
24 patients and providers about the appropriate

1 means of disposing of expired, damaged, or un-
2 usable medications; and

3 “(G) supporting initiatives that the Sec-
4 retary determines to be useful to fulfill the pur-
5 poses of the Internet website.

6 “(3) POSTING OF DRUG LABELING.—The Sec-
7 retary shall post on the Internet website established
8 under paragraph (1) the approved professional label-
9 ing and any required patient labeling of a drug ap-
10 proved under this section or licensed under such sec-
11 tion 351 not later than 21 days after the date the
12 drug is approved or licensed, including in a supple-
13 mental application with respect to a labeling change.

14 “(4) PRIVATE SECTOR RESOURCES.—To ensure
15 development of the Internet website by the date de-
16 scribed in paragraph (1), the Secretary may, on a
17 temporary or permanent basis, implement systems
18 or products developed by private entities.

19 “(5) AUTHORITY FOR CONTRACTS.—The Sec-
20 retary may enter into contracts with public and pri-
21 vate entities to fulfill the requirements of this sub-
22 section.

23 “(6) REVIEW.—The Advisory Committee on
24 Risk Communication under section 566 shall, on a
25 regular basis, perform a comprehensive review and

1 evaluation of the types of risk communication infor-
 2 mation provided on the Internet website established
 3 under paragraph (1) and, through other means,
 4 shall identify, clarify, and define the purposes and
 5 types of information available to facilitate the effi-
 6 cient flow of information to patients and providers,
 7 and shall recommend ways for the Food and Drug
 8 Administration to work with outside entities to help
 9 facilitate the dispensing of risk communication infor-
 10 mation to patients and providers.”.

11 **SEC. 210. ACTION PACKAGE FOR APPROVAL.**

12 Section 505(l) of the Federal Food, Drug, and Cos-
 13 metic Act (21 U.S.C. 355(l)) is amended by—

14 (1) redesignating paragraphs (1), (2), (3), (4),
 15 and (5) as subparagraphs (A), (B), (C), (D), and
 16 (E), respectively;

17 (2) striking “(l) Safety and” and inserting
 18 “(l)(1) Safety and”; and

19 (3) adding at the end the following:

20 “(2) ACTION PACKAGE FOR APPROVAL.—

21 “(A) ACTION PACKAGE.—The Secretary shall
 22 publish the action package for approval of an appli-
 23 cation under subsection (b) or section 351 of the
 24 Public Health Service Act on the Internet website of
 25 the Food and Drug Administration—

1 “(i) not later than 30 days after the date
2 of approval of such application for a drug no
3 active ingredient (including any ester or salt of
4 the active ingredient) of which has been ap-
5 proved in any other application under this sec-
6 tion or section 351 of the Public Health Service
7 Act; and

8 “(ii) not later than 30 days after the third
9 request for such action package for approval re-
10 ceived under section 552 of title 5, United
11 States Code, for any other drug.

12 “(B) IMMEDIATE PUBLICATION OF SUMMARY
13 REVIEW.—Notwithstanding subparagraph (A), the
14 Secretary shall publish, on the Internet website of
15 the Food and Drug Administration, the materials
16 described in subparagraph (C)(iv) not later than 48
17 hours after the date of approval of the drug, except
18 where such materials require redaction by the Sec-
19 retary.

20 “(C) CONTENTS.—An action package for ap-
21 proval of an application under subparagraph (A)
22 shall be dated and shall include the following:

23 “(i) Documents generated by the Food and
24 Drug Administration related to review of the
25 application.

1 “(ii) Documents pertaining to the format
2 and content of the application generated during
3 drug development.

4 “(iii) Labeling submitted by the applicant.

5 “(iv) A summary review that documents
6 conclusions from all reviewing disciplines about
7 the drug, noting any critical issues and dis-
8 agreements with the applicant and how they
9 were resolved, recommendation for action, and
10 an explanation of any nonconcurrence with re-
11 view conclusions.

12 “(v) If applicable, a separate review from
13 a supervisor who does not concur with the sum-
14 mary review.

15 “(vi) Identification by name of each officer
16 or employee of the Food and Drug Administra-
17 tion who—

18 “(I) participated in the decision to ap-
19 prove the application; and

20 “(II) consents to have his or her name
21 included in the package.

22 “(D) DISAGREEMENTS.—A scientific review of
23 an application is considered the work of the reviewer
24 and shall not be altered by management or the re-
25 viewer once final. Disagreements by team leaders,

1 division directors, or office directors with any or all
 2 of the major conclusions of a reviewer shall be docu-
 3 ment in a separate review or in an addendum to the
 4 review.

5 “(E) CONFIDENTIAL INFORMATION.—This
 6 paragraph does not authorize the disclosure of any
 7 trade secret or confidential commercial or financial
 8 information described in section 552(b)(4) of title 5,
 9 United States Code, unless the Secretary declares an
 10 emergency under section 319 of the Public Health
 11 Service Act and such disclosure is necessary to miti-
 12 gate the effects of such emergency.”.

13 **SEC. 211. RISK COMMUNICATION.**

14 Subchapter E of chapter V of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
 16 amended by adding at the end the following:

17 **“SEC. 566. RISK COMMUNICATION.**

18 “(a) ADVISORY COMMITTEE ON RISK COMMUNICA-
 19 TION.—

20 “(1) IN GENERAL.—The Secretary shall estab-
 21 lish an advisory committee to be known as the ‘Advi-
 22 sory Committee on Risk Communication’ (referred
 23 to in this section as the ‘Committee’).

24 “(2) DUTIES OF COMMITTEE.—The Committee
 25 shall advise the Commissioner on methods to effec-

1 tively communicate risks associated with the prod-
2 ucts regulated by the Food and Drug Administra-
3 tion.

4 “(3) MEMBERS.—The Secretary shall ensure
5 that the Committee is composed of experts on risk
6 communication, experts on the risks described in
7 subsection (b), and representatives of patient, con-
8 sumer, and health professional organizations.

9 “(4) PERMANENCE OF COMMITTEE.—Section
10 14 of the Federal Advisory Committee Act shall not
11 apply to the Committee established under this sub-
12 section.

13 “(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

14 “(1) IN GENERAL.—The Secretary shall partner
15 with professional medical societies, medical schools,
16 academic medical centers, and other stakeholders to
17 develop robust and multi-faceted systems for com-
18 munication to health care providers about emerging
19 postmarket drug risks.

20 “(2) PARTNERSHIPS.—The systems developed
21 under paragraph (1) shall—

22 “(A) account for the diversity among phy-
23 sicians in terms of practice, affinity for tech-
24 nology, and focus; and

1 “(B) include the use of existing commu-
 2 nication channels, including electronic commu-
 3 nications, in place at the Food and Drug Ad-
 4 ministration.”.

5 **SEC. 212. REFERRAL TO ADVISORY COMMITTEE.**

6 Section 505 of the Federal Food, Drug, and Cosmetic
 7 Act, as amended by section 202, is further amended by
 8 adding at the end the following:

9 “(p) REFERRAL TO ADVISORY COMMITTEE.—

10 “(1) IN GENERAL.—Prior to the approval of a
 11 drug no active ingredient (including any ester or salt
 12 of the active ingredient) of which has been approved
 13 in any other application under this section or section
 14 351 of the Public Health Service Act, the Secretary
 15 shall refer such drug to a Food and Drug Adminis-
 16 tration advisory committee for review at a meeting
 17 of such advisory committee.

18 “(2) EXCEPTION.—Notwithstanding paragraph
 19 (1), an advisory committee review of a drug de-
 20 scribed under such paragraph may occur within 1
 21 year after approval of such a drug if—

22 “(A) the clinical trial that formed the pri-
 23 mary basis of the safety and efficacy determina-
 24 tion was halted by a drug safety monitoring
 25 board or an Institutional Review Board before

1 its scheduled completion due to early unantici-
2 pated therapeutic results; or

3 “(B) the Secretary determines that it
4 would be beneficial to the public health.”.

5 **SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of enactment of this title, the Secretary shall issue
8 a report responding to the 2006 report of the Institute
9 of Medicine entitled “The Future of Drug Safety—Pro-
10 moting and Protecting the Health of the Public”.

11 (b) CONTENT OF REPORT.—The report issued by the
12 Secretary under subsection (a) shall include—

13 (1) an update on the implementation by the
14 Food and Drug Administration of its plan to re-
15 spond to the Institute of Medicine report described
16 under such subsection; and

17 (2) an assessment of how the Food and Drug
18 Administration has implemented—

19 (A) the recommendations described in such
20 Institute of Medicine report; and

21 (B) the requirement under paragraph (7)
22 of section 505(o) of the Federal Food, Drug,
23 and Cosmetic Act (as added by this title), that
24 the appropriate office responsible for reviewing
25 a drug and the office responsible for post-

1 approval safety with respect to the drug act to-
2 gether to assess, implement, and ensure compli-
3 ance with the requirements of such section
4 505(o).

5 **SEC. 214. EFFECTIVE DATE AND APPLICABILITY.**

6 (a) **EFFECTIVE DATES.—**

7 (1) **IN GENERAL.**—Except as provided in para-
8 graph (2), this subtitle shall take effect 180 days
9 after the date of enactment of this title.

10 (2) **USER FEES.**—The amendments made by
11 subsections (a) through (c) of section 207 shall take
12 effect on October 1, 2007.

13 (b) **DRUGS DEEMED TO HAVE RISK EVALUATION**
14 **AND MITIGATION STRATEGIES.—**

15 (1) **IN GENERAL.**—A drug that was approved
16 before the effective date of this subtitle shall be
17 deemed to have an approved risk evaluation and
18 mitigation strategy under section 505(o) of the Fed-
19 eral Food, Drug, and Cosmetic Act (as added by
20 this subtitle) if there are in effect on the effective
21 date of this subtitle restrictions on distribution or
22 use—

23 (A) required under section 314.520 or sec-
24 tion 601.42 of title 21, Code of Federal Regula-
25 tions; or

1 (B) otherwise agreed to by the applicant
2 and the Secretary for such drug.

3 (2) RISK EVALUATION AND MITIGATION STRAT-
4 EGY.—The approved risk evaluation and mitigation
5 strategy deemed in effect for a drug under para-
6 graph (1) shall consist of the elements described in
7 subparagraphs (A) and (B) of paragraph (3) of such
8 section 505(o) and any other additional elements
9 under paragraphs (4), (5), and (6) in effect for such
10 drug on the effective date of this subtitle.

11 (3) NOTIFICATION.—Not later than 30 days
12 after the effective date of this subtitle, the Secretary
13 shall notify the applicant for each drug described in
14 paragraph (1)—

15 (A) that such drug is deemed to have an
16 approved risk evaluation and mitigation strat-
17 egy pursuant to such paragraph; and

18 (B) of the date, which, unless a safety
19 issue with the drug arises, shall be no earlier
20 than 6 months after the applicant is so notified,
21 by which the applicant shall submit to the Sec-
22 retary an assessment of such approved strategy
23 under paragraph (7)(B) of such section 505(o),
24 except with respect to the drug Mifeprax
25 (mifepristone), such assessment shall be sub-

mitted 6 months after the applicant is so notified.

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement of a risk evaluation and mitigation strategy deemed in effect under paragraph (1) before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505(o).

(c) NO EFFECT ON VETERINARY MEDICINE.—This subtitle, and the amendments made by this subtitle, shall have no effect on the use of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 512(a)(5) of such Act.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

1 **“Subchapter I—Reagan-Udall Foundation for**
2 **the Food and Drug Administration**

3 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUN-**
4 **DATION.**

5 “(a) IN GENERAL.—A nonprofit corporation to be
6 known as the Reagan-Udall Foundation for the Food and
7 Drug Administration (referred to in this subchapter as the
8 ‘Foundation’) shall be established in accordance with this
9 section. The Foundation shall be headed by an Executive
10 Director, appointed by the members of the Board of Direc-
11 tors under subsection (e). The Foundation shall not be
12 an agency or instrumentality of the United States Govern-
13 ment.

14 “(b) PURPOSE OF FOUNDATION.—The purpose of
15 the Foundation is to advance the mission of the Food and
16 Drug Administration to modernize medical, veterinary,
17 food, food ingredient, and cosmetic product development,
18 accelerate innovation, and enhance product safety.

19 “(c) DUTIES OF THE FOUNDATION.—The Founda-
20 tion shall—

21 “(1) taking into consideration the Critical Path
22 reports and priorities published by the Food and
23 Drug Administration, identify unmet needs in the
24 development, manufacture, and evaluation of the
25 safety and effectiveness, including postapproval, of

1 devices, including diagnostics, biologics, and drugs,
2 and the safety of food, food ingredients, and cos-
3 metics;

4 “(2) establish goals and priorities in order to
5 meet the unmet needs identified in paragraph (1);

6 “(3) in consultation with the Secretary, identify
7 existing and proposed Federal intramural and extra-
8 mural research and development programs relating
9 to the goals and priorities established under para-
10 graph (2), coordinate Foundation activities with
11 such programs, and minimize Foundation duplica-
12 tion of existing efforts;

13 “(4) award grants to, or enter into contracts,
14 memoranda of understanding, or cooperative agree-
15 ments with, scientists and entities, which may in-
16 clude the Food and Drug Administration, university
17 consortia, public-private partnerships, institutions of
18 higher education, entities described in section
19 501(c)(3) of the Internal Revenue Code (and exempt
20 from tax under section 501(a) of such Code), and
21 industry, to efficiently and effectively advance the
22 goals and priorities established under paragraph (2);

23 “(5) recruit meeting participants and hold or
24 sponsor (in whole or in part) meetings as appro-

1 piate to further the goals and priorities established
2 under paragraph (2);

3 “(6) release and publish information and data
4 and, to the extent practicable, license, distribute,
5 and release material, reagents, and techniques to
6 maximize, promote, and coordinate the availability of
7 such material, reagents, and techniques for use by
8 the Food and Drug Administration, nonprofit orga-
9 nizations, and academic and industrial researchers
10 to further the goals and priorities established under
11 paragraph (2);

12 “(7) ensure that—

13 “(A) action is taken as necessary to obtain
14 patents for inventions developed by the Founda-
15 tion or with funds from the Foundation;

16 “(B) action is taken as necessary to enable
17 the licensing of inventions developed by the
18 Foundation or with funds from the Foundation;
19 and

20 “(C) executed licenses, memoranda of un-
21 derstanding, material transfer agreements, con-
22 tracts, and other such instruments, promote, to
23 the maximum extent practicable, the broadest
24 conversion to commercial and noncommercial
25 applications of licensed and patented inventions

of the Foundation to further the goals and priorities established under paragraph (2);

“(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency’s public health mission;

“(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

“(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

“(d) BOARD OF DIRECTORS.—

“(1) ESTABLISHMENT.—

“(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the ‘Board’), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

“(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

“(i) The Commissioner.

1 “(ii) The Director of the National In-
2 stitutes of Health.

3 “(iii) The Director of the Centers for
4 Disease Control and Prevention.

5 “(iv) The Director of the Agency for
6 Healthcare Research and Quality.

7 “(C) APPOINTED MEMBERS.—

8 “(i) IN GENERAL.—The ex officio
9 members of the Board under subparagraph
10 (B) shall, by majority vote, appoint to the
11 Board 12 individuals, from a list of can-
12 didates to be provided by the National
13 Academy of Sciences. Of such appointed
14 members—

15 “(I) 4 shall be representatives of
16 the general pharmaceutical, device,
17 food, cosmetic, and biotechnology in-
18 dustries;

19 “(II) 3 shall be representatives of
20 academic research organizations;

21 “(III) 2 shall be representatives
22 of Government agencies, including the
23 Food and Drug Administration and
24 the National Institutes of Health;

1 “(IV) 2 shall be representatives
2 of patient or consumer advocacy orga-
3 nizations; and

4 “(V) 1 shall be a representative
5 of health care providers.

6 “(ii) REQUIREMENT.—The ex officio
7 members shall ensure the Board member-
8 ship includes individuals with expertise in
9 areas including the sciences of developing,
10 manufacturing, and evaluating the safety
11 and effectiveness of devices, including
12 diagnostics, biologics, and drugs, and the
13 safety of food, food ingredients, and cos-
14 metics.

15 “(D) INITIAL MEETING.—

16 “(i) IN GENERAL.—Not later than 30
17 days after the date of the enactment of the
18 Enhancing Drug Safety and Innovation
19 Act of 2007, the Secretary shall convene a
20 meeting of the ex officio members of the
21 Board to—

22 “(I) incorporate the Foundation;
23 and

1 “(II) appoint the members of the
2 Board in accordance with subpara-
3 graph (C).

4 “(ii) SERVICE OF EX OFFICIO MEM-
5 BERS.—Upon the appointment of the
6 members of the Board under clause (i)(II),
7 the terms of service of the ex officio mem-
8 bers of the Board as members of the
9 Board shall terminate.

10 “(iii) CHAIR.—The ex officio members
11 of the Board under subparagraph (B) shall
12 designate an appointed member of the
13 Board to serve as the Chair of the Board.

14 “(2) DUTIES OF BOARD.—The Board shall—

15 “(A) establish bylaws for the Foundation
16 that—

17 “(i) are published in the Federal Reg-
18 ister and available for public comment;

19 “(ii) establish policies for the selection
20 of the officers, employees, agents, and con-
21 tractors of the Foundation;

22 “(iii) establish policies, including eth-
23 ical standards, for the acceptance, sollicita-
24 tion, and disposition of donations and
25 grants to the Foundation and for the dis-

1 position of the assets of the Foundation,
2 including appropriate limits on the ability
3 of donors to designate, by stipulation or re-
4 striction, the use or recipient of donated
5 funds;

6 “(iv) establish policies that would sub-
7 ject all employees, fellows, and trainees of
8 the Foundation to the conflict of interest
9 standards under section 208 of title 18,
10 United States Code;

11 “(v) establish licensing, distribution,
12 and publication policies that support the
13 widest and least restrictive use by the pub-
14 lic of information and inventions developed
15 by the Foundation or with Foundation
16 funds to carry out the duties described in
17 paragraphs (6) and (7) of subsection (c),
18 and may include charging cost-based fees
19 for published material produced by the
20 Foundation;

21 “(vi) specify principles for the review
22 of proposals and awarding of grants and
23 contracts that include peer review and that
24 are consistent with those of the Founda-
25 tion for the National Institutes of Health,

1 to the extent determined practicable and
2 appropriate by the Board;

3 “(vii) specify a cap on administrative
4 expenses for recipients of a grant, con-
5 tract, or cooperative agreement from the
6 Foundation;

7 “(viii) establish policies for the execu-
8 tion of memoranda of understanding and
9 cooperative agreements between the Foun-
10 dation and other entities, including the
11 Food and Drug Administration;

12 “(ix) establish policies for funding
13 training fellowships, whether at the Foun-
14 dation, academic or scientific institutions,
15 or the Food and Drug Administration, for
16 scientists, doctors, and other professionals
17 who are not employees of regulated indus-
18 try, to foster greater understanding of and
19 expertise in new scientific tools,
20 diagnostics, manufacturing techniques, and
21 potential barriers to translating basic re-
22 search into clinical and regulatory practice;

23 “(x) specify a process for annual
24 Board review of the operations of the
25 Foundation; and

1 “(xi) establish specific duties of the
2 Executive Director;

3 “(B) prioritize and provide overall direc-
4 tion to the activities of the Foundation;

5 “(C) evaluate the performance of the Exec-
6 utive Director; and

7 “(D) carry out any other necessary activi-
8 ties regarding the functioning of the Founda-
9 tion.

10 “(3) TERMS AND VACANCIES.—

11 “(A) TERM.—The term of office of each
12 member of the Board appointed under para-
13 graph (1)(C) shall be 4 years, except that the
14 terms of offices for the initial appointed mem-
15 bers of the Board shall expire on a staggered
16 basis as determined by the ex officio members.

17 “(B) VACANCY.—Any vacancy in the mem-
18 bership of the Board—

19 “(i) shall not affect the power of the
20 remaining members to execute the duties
21 of the Board; and

22 “(ii) shall be filled by appointment by
23 the appointed members described in para-
24 graph (1)(C) by majority vote.

1 “(C) PARTIAL TERM.—If a member of the
2 Board does not serve the full term applicable
3 under subparagraph (A), the individual ap-
4 pointed under subparagraph (B) to fill the re-
5 sulting vacancy shall be appointed for the re-
6 mainder of the term of the predecessor of the
7 individual.

8 “(D) SERVING PAST TERM.—A member of
9 the Board may continue to serve after the expi-
10 ration of the term of the member until a suc-
11 cessor is appointed.

12 “(4) COMPENSATION.—Members of the Board
13 may not receive compensation for service on the
14 Board. Such members may be reimbursed for travel,
15 subsistence, and other necessary expenses incurred
16 in carrying out the duties of the Board, as set forth
17 in the bylaws issued by the Board.

18 “(e) INCORPORATION.—The ex officio members of the
19 Board shall serve as incorporators and shall take whatever
20 actions necessary to incorporate the Foundation.

21 “(f) NONPROFIT STATUS.—The Foundation shall be
22 considered to be a corporation under section 501(c) of the
23 Internal Revenue Code of 1986, and shall be subject to
24 the provisions of such section.

25 “(g) EXECUTIVE DIRECTOR.—

1 “(1) IN GENERAL.—The Board shall appoint an
 2 Executive Director who shall serve at the pleasure of
 3 the Board. The Executive Director shall be respon-
 4 sible for the day-to-day operations of the Foundation
 5 and shall have such specific duties and responsibil-
 6 ities as the Board shall prescribe.

7 “(2) COMPENSATION.—The compensation of
 8 the Executive Director shall be fixed by the Board
 9 but shall not be greater than the compensation of
 10 the Commissioner.

11 “(h) ADMINISTRATIVE POWERS.—In carrying out
 12 this subchapter, the Board, acting through the Executive
 13 Director, may—

14 “(1) adopt, alter, and use a corporate seal,
 15 which shall be judicially noticed;

16 “(2) hire, promote, compensate, and discharge
 17 1 or more officers, employees, and agents, as may be
 18 necessary, and define their duties;

19 “(3) prescribe the manner in which—

20 “(A) real or personal property of the
 21 Foundation is acquired, held, and transferred;

22 “(B) general operations of the Foundation
 23 are to be conducted; and

24 “(C) the privileges granted to the Board
 25 by law are exercised and enjoyed;

1 “(4) with the consent of the applicable executive
2 department or independent agency, use the informa-
3 tion, services, and facilities of such department or
4 agencies in carrying out this section;

5 “(5) enter into contracts with public and pri-
6 vate organizations for the writing, editing, printing,
7 and publishing of books and other material;

8 “(6) hold, administer, invest, and spend any
9 gift, devise, or bequest of real or personal property
10 made to the Foundation under subsection (i);

11 “(7) enter into such other contracts, leases, co-
12 operative agreements, and other transactions as the
13 Board considers appropriate to conduct the activities
14 of the Foundation;

15 “(8) modify or consent to the modification of
16 any contract or agreement to which it is a party or
17 in which it has an interest under this subchapter;

18 “(9) take such action as may be necessary to
19 obtain patents and licenses for devices and proce-
20 dures developed by the Foundation and its employ-
21 ees;

22 “(10) sue and be sued in its corporate name,
23 and complain and defend in courts of competent ju-
24 risdiction;

1 “(11) appoint other groups of advisors as may
2 be determined necessary to carry out the functions
3 of the Foundation; and

4 “(12) exercise other powers as set forth in this
5 section, and such other incidental powers as are nec-
6 essary to carry out its powers, duties, and functions
7 in accordance with this subchapter.

8 “(i) ACCEPTANCE OF FUNDS FROM OTHER
9 SOURCES.—The Executive Director may solicit and accept
10 on behalf of the Foundation, any funds, gifts, grants, de-
11 vises, or bequests of real or personal property made to the
12 Foundation, including from private entities, for the pur-
13 poses of carrying out the duties of the Foundation.

14 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
15 Government employees may serve on committees advisory
16 to the Foundation and otherwise cooperate with and assist
17 the Foundation in carrying out its functions, so long as
18 such employees do not direct or control Foundation activi-
19 ties.

20 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
21 LOWSHIPS.—

22 “(1) DETAIL FROM FEDERAL AGENCIES.—Fed-
23 eral Government employees may be detailed from
24 Federal agencies with or without reimbursement to
25 those agencies to the Foundation at any time, and

1 such detail shall be without interruption or loss of
2 civil service status or privilege. Each such employee
3 shall abide by the statutory, regulatory, ethical, and
4 procedural standards applicable to the employees of
5 the agency from which such employee is detailed and
6 those of the Foundation.

7 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
8 FEDERAL EMPLOYEES.—

9 “(A) FOUNDATION.—The Executive Direc-
10 tor of the Foundation may accept the services
11 of employees detailed from Federal agencies
12 with or without reimbursement to those agen-
13 cies.

14 “(B) FOOD AND DRUG ADMINISTRATION.—
15 The Commissioner may accept the uncompen-
16 sated services of Foundation fellows or trainees.
17 Such services shall be considered to be under-
18 taking an activity under contract with the Sec-
19 retary as described in section 708.

20 “(1) ANNUAL REPORTS.—

21 “(1) REPORTS TO FOUNDATION.—Any recipient
22 of a grant, contract, fellowship, memorandum of un-
23 derstanding, or cooperative agreement from the
24 Foundation under this section shall submit to the
25 Foundation a report on an annual basis for the du-

1 ration of such grant, contract, fellowship, memo-
2 randum of understanding, or cooperative agreement,
3 that describes the activities carried out under such
4 grant, contract, fellowship, memorandum of under-
5 standing, or cooperative agreement.

6 “(2) REPORT TO CONGRESS AND THE FDA.—
7 Beginning with fiscal year 2009, the Executive Di-
8 rector shall submit to Congress and the Commis-
9 sioner an annual report that—

10 “(A) describes the activities of the Foun-
11 dation and the progress of the Foundation in
12 furthering the goals and priorities established
13 under subsection (c)(2), including the practical
14 impact of the Foundation on regulated product
15 development;

16 “(B) provides a specific accounting of the
17 source and use of all funds used by the Foun-
18 dation to carry out such activities; and

19 “(C) provides information on how the re-
20 sults of Foundation activities could be incor-
21 porated into the regulatory and product review
22 activities of the Food and Drug Administration.

23 “(m) SEPARATION OF FUNDS.—The Executive Di-
24 rector shall ensure that the funds received from the Treas-

1 ury are held in separate accounts from funds received
 2 from entities under subsection (i).

3 “(n) FUNDING.—From amounts appropriated to the
 4 Food and Drug Administration for each fiscal year, the
 5 Commissioner shall transfer not less than \$500,000 and
 6 not more than \$1,250,000, to the Foundation to carry out
 7 subsections (a), (b), and (d) through (m).”.

8 (b) OTHER FOUNDATION PROVISIONS.—Chapter VII
 9 (21 U.S.C. 371 et seq.) (as amended by subsection (a))
 10 is amended by adding at the end the following:

11 **“SEC. 771. LOCATION OF FOUNDATION.**

12 “The Foundation shall, if practicable, be located not
 13 more than 20 miles from the District of Columbia.

14 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
 15 **TRATION.**

16 “(a) IN GENERAL.—The Commissioner shall receive
 17 and assess the report submitted to the Commissioner by
 18 the Executive Director of the Foundation under section
 19 770(l)(2).

20 “(b) REPORT TO CONGRESS.—Beginning with fiscal
 21 year 2009, the Commissioner shall submit to Congress an
 22 annual report summarizing the incorporation of the infor-
 23 mation provided by the Foundation in the report described
 24 under section 770(l)(2) and by other recipients of grants,
 25 contracts, memoranda of understanding, or cooperative

1 agreements into regulatory and product review activities
2 of the Food and Drug Administration.

3 “(c) EXTRAMURAL GRANTS.—The provisions of this
4 subchapter shall have no effect on any grant, contract,
5 memorandum of understanding, or cooperative agreement
6 between the Food and Drug Administration and any other
7 entity entered into before, on, or after the date of enact-
8 ment of the Enhancing Drug Safety and Innovation Act
9 of 2007.”.

10 (c) CONFORMING AMENDMENT.—Section 742(b) of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379l(b)) is amended by adding at the end the following:
13 “Any such fellowships and training programs under this
14 section or under section 770(d)(2)(A)(ix) may include pro-
15 vision by such scientists and physicians of services on a
16 voluntary and uncompensated basis, as the Secretary de-
17 termines appropriate. Such scientists and physicians shall
18 be subject to all legal and ethical requirements otherwise
19 applicable to officers or employees of the Department of
20 Health and Human Services.”.

21 **SEC. 222. OFFICE OF THE CHIEF SCIENTIST.**

22 Chapter IX of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 391 et seq.) is amended by adding at the
24 end the following:

1 **“SEC. 910. OFFICE OF THE CHIEF SCIENTIST.**

2 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
3 retary shall establish within the Office of the Commis-
4 sioner an office to be known as the Office of the Chief
5 Scientist. The Secretary shall appoint a Chief Scientist to
6 lead such Office.

7 “(b) DUTIES OF THE OFFICE.—The Office of the
8 Chief Scientist shall—

9 “(1) oversee, coordinate, and ensure quality and
10 regulatory focus of the intramural research pro-
11 grams of the Food and Drug Administration;

12 “(2) track and, to the extent necessary, coordi-
13 nate intramural research awards made by each cen-
14 ter of the Administration or science-based office
15 within the Office of the Commissioner, and ensure
16 that there is no duplication of research efforts sup-
17 ported by the Reagan-Udall Foundation for the
18 Food and Drug Administration;

19 “(3) develop and advocate for a budget to sup-
20 port intramural research;

21 “(4) develop a peer review process by which in-
22 tramural research can be evaluated; and

23 “(5) identify and solicit intramural research
24 proposals from across the Food and Drug Adminis-
25 tration through an advisory board composed of em-
26 ployees of the Administration that shall include—

1 “(A) representatives of each of the centers
 2 and the science-based offices within the Office
 3 of the Commissioner; and

4 “(B) experts on trial design, epidemiology,
 5 demographics, pharmacovigilance, basic science,
 6 and public health.”.

7 **Subtitle C—Clinical Trials**

8 **SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA** 9 **BANK.**

10 (a) IN GENERAL.—Section 402 of the Public Health
 11 Service Act (42 U.S.C. 282) is amended by—

12 (1) redesignating subsections (j) and (k) as
 13 subsections (k) and (l), respectively; and

14 (2) inserting after subsection (i) the following:

15 “(j) EXPANDED CLINICAL TRIAL REGISTRY DATA
 16 BANK.—

17 “(1) DEFINITIONS; REQUIREMENT.—

18 “(A) DEFINITIONS.—In this subsection:

19 “(i) APPLICABLE DEVICE CLINICAL
 20 TRIAL.—The term ‘applicable device clin-
 21 ical trial’ means—

22 “(I) a prospective study of health
 23 outcomes comparing an intervention
 24 against a control in human subjects
 25 intended to support an application

under section 515 or 520(m), or a report under section 510(k), of the Federal Food, Drug, and Cosmetic Act (other than a limited study to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device); and

“(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

“(ii) APPLICABLE DRUG CLINICAL TRIAL.—

“(I) IN GENERAL.—The term ‘applicable drug clinical trial’ means a controlled clinical investigation, other than a phase I clinical investigation, of a product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

“(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term ‘clinical investigation’ has

1 the meaning given that term in sec-
2 tion 312.3 of title 21, Code of Federal
3 Regulations.

4 “(III) PHASE I.—The term
5 ‘phase I’ has the meaning given that
6 term in section 312.21 of title 21,
7 Code of Federal Regulations.

8 “(iii) CLINICAL TRIAL INFORMA-
9 TION.—The term ‘clinical trial information’
10 means those data elements that are nec-
11 essary to complete an entry in the clinical
12 trial registry data bank under paragraph
13 (2).

14 “(iv) COMPLETION DATE.—The term
15 ‘completion date’ means, with respect to an
16 applicable drug clinical trial or an applica-
17 ble device clinical trial, the date on which
18 the last patient enrolled in the clinical trial
19 has completed his or her last medical visit
20 of the clinical trial, whether the clinical
21 trial concluded according to the
22 prespecified protocol plan or was termi-
23 nated.

24 “(v) DEVICE.—The term ‘device’
25 means a device as defined in section

1 201(h) of the Federal Food, Drug, and
2 Cosmetic Act.

3 “(vi) DRUG.—The term ‘drug’ means
4 a drug as defined in section 201(g) of the
5 Federal Food, Drug, and Cosmetic Act or
6 a biological product as defined in section
7 351 of this Act.

8 “(vii) RESPONSIBLE PARTY.—The
9 term ‘responsible party’, with respect to a
10 clinical trial of a drug or device, means—

11 “(I) the sponsor of the clinical
12 trial (as defined in section 50.3 of
13 title 21, Code of Federal Regulations
14 (or any successor regulations)) or the
15 principal investigator of such clinical
16 trial if so designated by such sponsor;
17 or

18 “(II) if no sponsor exists, the
19 grantee, contractor, or awardee for a
20 trial funded by a Federal agency or
21 the principal investigator of such clin-
22 ical trial if so designated by such
23 grantee, contractor, or awardee.

24 “(B) REQUIREMENT.—The Secretary shall
25 develop a mechanism by which—

1 “(i) the responsible party for each ap-
2 plicable drug clinical trial and applicable
3 device clinical trial shall submit the iden-
4 tity and contact information of such re-
5 sponsible party to the Secretary at the
6 time of submission of clinical trial informa-
7 tion under paragraph (2); and

8 “(ii) other Federal agencies may iden-
9 tify the responsible party for an applicable
10 drug clinical trial or applicable device clin-
11 ical trial.

12 “(2) EXPANSION OF CLINICAL TRIAL REGISTRY
13 DATA BANK WITH RESPECT TO CLINICAL TRIAL IN-
14 FORMATION.—

15 “(A) IN GENERAL.—

16 “(i) EXPANSION OF DATA BANK.—To
17 enhance patient enrollment and provide a
18 mechanism to track subsequent progress of
19 clinical trials, the Secretary, acting
20 through the Director of NIH, shall expand,
21 in accordance with this subsection, the
22 clinical trials registry of the data bank de-
23 scribed under subsection (i)(3)(A) (re-
24 ferred to in this subsection as the ‘registry
25 data bank’). The Director of NIH shall en-

1 sure that the registry data bank is made
2 publicly available through the Internet.

3 “(ii) CONTENT.—Not later than 18
4 months after the date of enactment of the
5 Enhancing Drug Safety and Innovation
6 Act of 2007, and after notice and com-
7 ment, the Secretary shall promulgate regu-
8 lations to expand the registry data bank to
9 require the submission to the registry data
10 bank of clinical trial information for appli-
11 cable drug clinical trials and applicable de-
12 vice clinical trials that—

13 “(I) conforms to the Inter-
14 national Clinical Trials Registry Plat-
15 form trial registration data set of the
16 World Health Organization;

17 “(II) includes the city, State, and
18 zip code for each clinical trial location,
19 or a toll-free number through which
20 such location information may be
21 accessed;

22 “(III) if the drug is not approved
23 under section 505 of the Federal
24 Food, Drug, and Cosmetic Act or li-
25 censed under section 351 of this Act,

1 specifies whether or not there is ex-
2 panded access to the drug under sec-
3 tion 561 of the Federal Food, Drug,
4 and Cosmetic Act for those who do
5 not qualify for enrollment in the clin-
6 ical trial and how to obtain informa-
7 tion about such access;

8 “(IV) requires the inclusion of
9 such other data elements to the reg-
10 istry data bank as appropriate; and

11 “(V) becomes effective 90 days
12 after issuance of the final rule.

13 “(B) FORMAT AND STRUCTURE.—

14 “(i) SEARCHABLE CATEGORIES.—The
15 Director of NIH shall ensure that the pub-
16 lic may search the entries in the registry
17 data bank by 1 or more of the following
18 criteria:

19 “(I) The disease or condition
20 being studied in the clinical trial,
21 using Medical Subject Headers
22 (MeSH) descriptors.

23 “(II) The treatment being stud-
24 ied in the clinical trial.

1 “(III) The location of the clinical
2 trial.

3 “(IV) The age group studied in
4 the clinical trial, including pediatric
5 subpopulations.

6 “(V) The study phase of the clinical trial.

8 “(VI) The source of support for
9 the clinical trial, which may be the
10 National Institutes of Health or other
11 Federal agency, a private industry
12 source, or a university or other organization.
13

14 “(VII) The recruitment status of
15 the clinical trial.

16 “(VIII) The National Clinical
17 Trial number or other study identification for the clinical trial.
18

19 “(ii) FORMAT.—The Director of the
20 NIH shall ensure that the registry data
21 bank is easily used by the public, and that
22 entries are easily compared.

23 “(C) DATA SUBMISSION.—The responsible
24 party for an applicable drug clinical trial shall
25 submit to the Director of NIH for inclusion in

1 the registry data bank the clinical trial informa-
2 tion described in subparagraph (A)(ii).

3 “(D) TRUTHFUL CLINICAL TRIAL INFOR-
4 MATION.—

5 “(i) IN GENERAL.—The clinical trial
6 information submitted by a responsible
7 party under this paragraph shall not be
8 false or misleading in any particular.

9 “(ii) EFFECT.—Clause (i) shall not
10 have the effect of requiring clinical trial in-
11 formation with respect to an applicable
12 drug clinical trial or an applicable device
13 clinical trial to include information from
14 any source other than such clinical trial in-
15 volved.

16 “(E) CHANGES IN CLINICAL TRIAL STA-
17 TUS.—

18 “(i) ENROLLMENT.—The responsible
19 party for an applicable drug clinical trial
20 or an applicable device clinical trial shall
21 update the enrollment status not later than
22 30 days after the enrollment status of such
23 clinical trial changes.

24 “(ii) COMPLETION.—The responsible
25 party for an applicable drug clinical trial

1 or applicable device clinical trial shall re-
2 port to the Director of NIH that such clin-
3 ical trial is complete not later than 30 days
4 after the completion date of the clinical
5 trial.

6 “(F) TIMING OF SUBMISSION.—The clin-
7 ical trial information for an applicable drug
8 clinical trial or an applicable device clinical trial
9 required to be submitted under this paragraph
10 shall be submitted not later than 21 days after
11 the first patient is enrolled in such clinical trial.

12 “(G) POSTING OF DATA.—

13 “(i) APPLICABLE DRUG CLINICAL
14 TRIAL.—The Director of NIH shall ensure
15 that clinical trial information for an appli-
16 cable drug clinical trial submitted in ac-
17 cordance with this paragraph is posted
18 publicly within 30 days of such submission.

19 “(ii) APPLICABLE DEVICE CLINICAL
20 TRIAL.—The Director of NIH shall ensure
21 that clinical trial information for an appli-
22 cable device clinical trial submitted in ac-
23 cordance with this paragraph is posted
24 publicly within 30 days of clearance under
25 section 510(k) of the Federal Food, Drug,

1 and Cosmetic Act, or approval under sec-
2 tion 515 or section 520(m) of such Act, as
3 applicable.

4 “(H) VOLUNTARY SUBMISSIONS.—A re-
5 sponsible party for a clinical trial that is not an
6 applicable drug clinical trial or an applicable de-
7 vice clinical trial may submit clinical trial infor-
8 mation to the registry data bank in accordance
9 with this subsection.

10 “(3) EXPANSION OF REGISTRY DATA BANK TO
11 INCLUDE RESULTS OF CLINICAL TRIALS.—

12 “(A) LINKING REGISTRY DATA BANK TO
13 EXISTING RESULTS.—

14 “(i) IN GENERAL.—Beginning not
15 later than 90 days after the date of enact-
16 ment of the Enhancing Drug Safety and
17 Innovation Act of 2007, for those clinical
18 trials that form the primary basis of an ef-
19 ficacy claim or are conducted after the
20 drug involved is approved or after the de-
21 vice involved is cleared or approved, the
22 Secretary shall ensure that the registry
23 data bank includes links to results infor-
24 mation for such clinical trial—

1 “(I) not earlier than 30 days
2 after the date of the approval of the
3 drug involved or clearance or approval
4 of the device involved; or

5 “(II) not later than 30 days after
6 such information becomes publicly
7 available, as applicable.

8 “(ii) REQUIRED INFORMATION.—

9 “(I) FDA INFORMATION.—The
10 Secretary shall ensure that the reg-
11 istry data bank includes links to the
12 following information:

13 “(aa) If an advisory com-
14 mittee considered at a meeting
15 an applicable drug clinical trial
16 or an applicable device clinical
17 trial, any posted Food and Drug
18 Administration summary docu-
19 ment regarding such applicable
20 drug clinical trial or applicable
21 clinical device trial.

22 “(bb) If an applicable drug
23 clinical trial was conducted under
24 section 505A or 505B of the
25 Federal Food, Drug, and Cos-

1 metic Act, a link to the posted
2 Food and Drug Administration
3 assessment of the results of such
4 trial.

5 “(cc) Food and Drug Ad-
6 ministration public health
7 advisories regarding the drug or
8 device that is the subject of the
9 applicable drug clinical trial or
10 applicable device clinical trial, re-
11 spectively, if any.

12 “(dd) For an applicable
13 drug clinical trial, the Food and
14 Drug Administration action
15 package for approval document
16 required under section 505(l)(2)
17 of the Food Drug and Cosmetic
18 Act.

19 “(ee) For an applicable de-
20 vice clinical trial, in the case of a
21 premarket application, the de-
22 tailed summary of information
23 respecting the safety and effec-
24 tiveness of the device required
25 under section 520(h)(1) of the

1 Federal Food, Drug, and Cos-
2 metic Act, or, in the case of a re-
3 port under section 510(k) of such
4 Act, the section 510(k) summary
5 of the safety and effectiveness
6 data required under section
7 807.95(d) of title 21, Code of
8 Federal Regulations (or any suc-
9 cessor regulations).

10 “(II) NIH INFORMATION.—The
11 Secretary shall ensure that the reg-
12 istry data bank includes links to the
13 following information:

14 “(aa) Medline citations to
15 any publications regarding each
16 applicable drug clinical trial and
17 applicable device clinical trial.

18 “(bb) The entry for the drug
19 that is the subject of an applica-
20 ble drug clinical trial in the Na-
21 tional Library of Medicine data-
22 base of structured product labels,
23 if available.

24 “(iii) RESULTS FOR EXISTING DATA
25 BANK ENTRIES.—The Secretary may in-

1 clude the links described in clause (ii) for
2 data bank entries for clinical trials sub-
3 mitted to the data bank prior to enactment
4 of the Enhancing Drug Safety and Innova-
5 tion Act of 2007, as available.

6 “(B) FEASIBILITY STUDY.—The Director
7 of NIH shall—

8 “(i) conduct a study to determine the
9 best, validated methods of making the re-
10 sults of clinical trials publicly available
11 after the approval of the drug that is the
12 subject of an applicable drug clinical trial;
13 and

14 “(ii) not later than 18 months after
15 initiating such study, submit to the Sec-
16 retary any findings and recommendations
17 of such study.

18 “(C) NEGOTIATED RULEMAKING.—

19 “(i) IN GENERAL.—The Secretary
20 shall establish a negotiated rulemaking
21 process pursuant to subchapter IV of chap-
22 ter 5 of title 5, United States Code, to de-
23 termine, for applicable drug clinical
24 trials—

1 “(I) how to ensure quality and
2 validate methods of expanding the
3 registry data bank to include clinical
4 trial results information for trials not
5 within the scope of this Act;

6 “(II) the clinical trials of which
7 the results information is appropriate
8 for adding to the expanded registry
9 data bank; and

10 “(III) the appropriate timing of
11 the posting of such results informa-
12 tion.

13 “(ii) TIME REQUIREMENT.—The proc-
14 ess described in paragraph (1) shall be
15 conducted in a timely manner to ensure
16 that—

17 “(I) any recommendation for a
18 proposed rule—

19 “(aa) is provided to the Sec-
20 retary not later than 21 months
21 after the date of the enactment
22 of the Enhancing Drug Safety
23 and Innovation Act of 2007; and

1 “(bb) includes an assess-
2 ment of the benefits and costs of
3 the recommendation; and

4 “(II) a final rule is promulgated
5 not later than 30 months after the
6 date of the enactment of the Enhanc-
7 ing Drug Safety and Innovation Act
8 of 2007, taking into account the rec-
9 ommendations under subclause (I)
10 and the results of the feasibility study
11 conducted under subparagraph (B).

12 “(iii) REPRESENTATION ON NEGO-
13 TIATED RULEMAKING COMMITTEE.—The
14 negotiated rulemaking committee estab-
15 lished by the Secretary pursuant to clause
16 (i) shall include members representing—

17 “(I) the Food and Drug Adminis-
18 tration;

19 “(II) the National Institutes of
20 Health;

21 “(III) other Federal agencies as
22 the Secretary determines appropriate;

23 “(IV) patient advocacy and
24 health care provider groups;

1 “(V) the pharmaceutical indus-
2 try;

3 “(VI) contract clinical research
4 organizations;

5 “(VII) the International Com-
6 mittee of Medical Journal Editors;
7 and

8 “(VIII) other interested parties,
9 including experts in privacy protec-
10 tion, pediatrics, health information
11 technology, health literacy, commu-
12 nication, clinical trial design and im-
13 plementation, and health care ethics.

14 “(iv) CONTENT OF REGULATIONS.—
15 The regulations promulgated pursuant to
16 clause (i) shall establish—

17 “(I) procedures to determine
18 which clinical trials results informa-
19 tion data elements shall be included in
20 the registry data bank, taking into ac-
21 count the needs of different popu-
22 lations of users of the registry data
23 bank;

1 “(II) a standard format for the
2 submission of clinical trials results to
3 the registry data bank;

4 “(III) a standard procedure for
5 the submission of clinical trial results
6 information, including the timing of
7 submission and the timing of posting
8 of results information, to the registry
9 data bank, taking into account the
10 possible impacts on publication of
11 manuscripts based on the clinical
12 trial;

13 “(IV) a standard procedure for
14 the verification of clinical trial results
15 information, including ensuring that
16 free text data elements are non-pro-
17 motional; and

18 “(V) an implementation plan for
19 the prompt inclusion of clinical trials
20 results information in the registry
21 data bank.

22 “(D) CONSIDERATION OF WORLD HEALTH
23 ORGANIZATION DATA SET.—The Secretary shall
24 consider the status of the consensus data ele-
25 ments set for reporting clinical trial results of

1 the World Health Organization when promul-
2 gating the regulations under subparagraph (C).

3 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
4 MATION.—

5 “(i) IN GENERAL.—The clinical trial
6 information submitted by a responsible
7 party under this paragraph shall not be
8 false or misleading in any particular.

9 “(ii) EFFECT.—Clause (i) shall not
10 have the effect of requiring clinical trial in-
11 formation with respect to an applicable
12 drug clinical trial or an applicable device
13 clinical trial to include information from
14 any source other than such clinical trial in-
15 volved.

16 “(F) WAIVERS REGARDING CERTAIN CLIN-
17 ICAL TRIAL RESULTS.—The Secretary may
18 waive any applicable requirements of this para-
19 graph for an applicable drug clinical trial or an
20 applicable device clinical trial, upon a written
21 request from the responsible person, if the Sec-
22 retary determines that extraordinary cir-
23 cumstances justify the waiver and that pro-
24 viding the waiver is in the public interest, con-
25 sistent with the protection of public health, or

1 in the interest of national security. Not later
2 than 30 days after any part of a waiver is
3 granted, the Secretary shall notify, in writing,
4 the appropriate committees of Congress of the
5 waiver and provide an explanation for why the
6 waiver was granted.

7 “(4) COORDINATION AND COMPLIANCE.—

8 “(A) CLINICAL TRIALS SUPPORTED BY
9 GRANTS FROM FEDERAL AGENCIES.—

10 “(i) IN GENERAL.—No Federal agen-
11 cy may release funds under a research
12 grant to an awardee who has not complied
13 with paragraph (2) for any applicable drug
14 clinical trial or applicable device clinical
15 trial for which such person is the respon-
16 sible party.

17 “(ii) GRANTS FROM CERTAIN FED-
18 ERAL AGENCIES.—If an applicable drug
19 clinical trial or applicable device clinical
20 trial is funded in whole or in part by a
21 grant from the Food and Drug Adminis-
22 tration, National Institutes of Health, the
23 Agency for Healthcare Research and Qual-
24 ity, or the Department of Veterans Affairs,
25 any grant or progress report forms re-

1 quired under such grant shall include a
2 certification that the responsible party has
3 made all required submissions to the Di-
4 rector of NIH under paragraph (2).

5 “(iii) VERIFICATION BY FEDERAL
6 AGENCIES.—The heads of the agencies re-
7 ferred to in clause (ii), as applicable, shall
8 verify that the clinical trial information for
9 each applicable drug clinical trial or appli-
10 cable device clinical trial for which a grant-
11 ee is the responsible party has been sub-
12 mitted under paragraph (2) before releas-
13 ing any remaining funding for a grant or
14 funding for a future grant to such grantee.

15 “(iv) NOTICE AND OPPORTUNITY TO
16 REMEDY.—If the head of an agency re-
17 ferred to in clause (ii), as applicable,
18 verifies that a grantee has not submitted
19 clinical trial information as described in
20 clause (iii), such agency head shall provide
21 notice to such grantee of such non-compli-
22 ance and allow such grantee 30 days to
23 correct such non-compliance and submit
24 the required clinical trial information.

1 “(v) CONSULTATION WITH OTHER
2 FEDERAL AGENCIES.—The Secretary
3 shall—

4 “(I) consult with other agencies
5 that conduct research involving
6 human subjects in accordance with
7 any section of part 46 of title 45,
8 Code of Federal Regulations (or any
9 successor regulations), to determine if
10 any such research is an applicable
11 drug clinical trial or an applicable de-
12 vice clinical trial under paragraph (1);
13 and

14 “(II) develop with such agencies
15 procedures comparable to those de-
16 scribed in clauses (ii), (iii), and (iv) to
17 ensure that clinical trial information
18 for such applicable drug clinical trials
19 and applicable device clinical trial is
20 submitted under paragraph (2).

21 “(B) CERTIFICATION TO ACCOMPANY
22 DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUB-
23 MISSIONS.—At the time of submission of an ap-
24 plication under section 505 of the Federal
25 Food, Drug, and Cosmetic Act, section 515 of

1 such Act, section 520(m) of such Act, or section
2 351 of this Act, or submission of a report under
3 section 510(k) of such Act, such application or
4 submission shall be accompanied by a certifi-
5 cation that all applicable requirements of this
6 subsection have been met. Where available, such
7 certification shall include the appropriate Na-
8 tional Clinical Trial control numbers.

9 “(C) VERIFICATION OF SUBMISSION PRIOR
10 TO POSTING.—In the case of clinical trial infor-
11 mation that is submitted under paragraph (2),
12 but is not made publicly available pending regu-
13 latory approval or clearance, as applicable, the
14 Director of NIH shall respond to inquiries from
15 other Federal agencies and peer-reviewed sci-
16 entific journals to confirm that such clinical
17 trial information has been submitted but has
18 not yet been posted.

19 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
20 TRIAL INFORMATION.—

21 “(A) IN GENERAL.—Nothing in this sub-
22 section (or under section 552 of title 5, United
23 States Code) shall require the Secretary to pub-
24 licly disclose, from any record or source other
25 than the registry data bank expanded under

1 this subsection, information described in sub-
2 paragraph (B).

3 “(B) INFORMATION DESCRIBED.—Infor-
4 mation described in this subparagraph is—

5 “(i) information submitted to the Di-
6 rector of NIH under this subsection, or in-
7 formation of the same general nature as
8 (or integrally associated with) the informa-
9 tion so submitted; and

10 “(ii) not otherwise publicly available,
11 including because it is protected from dis-
12 closure under section 552 of title 5, United
13 States Code.

14 “(6) AUTHORIZATION OF APPROPRIATIONS.—
15 There are authorized to be appropriated to carry out
16 this subsection \$10,000,000 for each fiscal year.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) PROHIBITED ACTS.—Section 301 of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 331) is amended by adding at the end the following:

21 “(jj)(1) The failure to submit the certification re-
22 quired by section 402(j)(4)(B) of the Public Health Serv-
23 ice Act, or knowingly submitting a false certification under
24 such section.

1 “(2) The submission of clinical trial information
2 under subsection (i) or (j) of section 402 of the Public
3 Health Service Act that is promotional or false or mis-
4 leading in any particular under paragraph (2) or (3) of
5 such subsection (j).”.

6 (2) CIVIL MONEY PENALTIES.—Section 303(f)
7 of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 333(f)), as amended by section 203, is fur-
9 ther amended by—

10 (A) redesignating paragraphs (4), (5), and
11 (6) as paragraphs (5), (6), and (7), respec-
12 tively;

13 (B) inserting after paragraph (3) the fol-
14 lowing:

15 “(4) Any person who violates section 301(jj) shall be
16 subject to a civil monetary penalty of not more than
17 \$10,000 for the first violation, and not more than \$20,000
18 for each subsequent violation.”;

19 (C) in paragraph (2)(C), by striking
20 “paragraph (4)(A)” and inserting “paragraph
21 (5)(A)”;

22 (D) in paragraph (5), as so redesignated,
23 by striking “paragraph (1), (2), or (3)” each
24 place it appears and inserting “paragraph (1),
25 (2), (3), or (4)”;

1 (E) in paragraph (7), as so redesignated,
2 by striking “paragraph (5)” each place it ap-
3 pears and inserting “paragraph (6)”.

4 (3) NEW DRUGS AND DEVICES.—

5 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
6 tion 505(i) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355(i)) is amended in
8 paragraph (4), by adding at the end the fol-
9 lowing: “The Secretary shall update such regu-
10 lations to require inclusion in the informed con-
11 sent form a statement that clinical trial infor-
12 mation for such clinical investigation has been
13 or will be submitted for inclusion in the registry
14 data bank pursuant to subsections (i) and (j) of
15 section 402 of the Public Health Service Act.”.

16 (B) NEW DRUG APPLICATIONS.—Section
17 505(b) of the Federal, Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(b)) is amended by
19 adding at the end the following:

20 “(6) An application submitted under this sub-
21 section shall be accompanied by the certification re-
22 quired under section 402(j)(4)(B) of the Public
23 Health Service Act. Such certification shall not be
24 considered an element of such application.”.

1 (C) DEVICE REPORTS UNDER SECTION
2 510(k).—Section 510(k) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360(k)) is
4 amended by adding at the end the following:
5 “A notification submitted under this subsection that con-
6 tains clinical trial data for an applicable device clinical
7 trial (as defined in section 402(j)(1) of the Public Health
8 Service Act) shall be accompanied by the certification re-
9 quired under section 402(j)(4)(B) of such Act. Such cer-
10 tification shall not be considered an element of such notifi-
11 cation.”.

12 (D) DEVICE PREMARKET APPROVAL APPLI-
13 CATION.—Section 515(c) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
15 amended—

16 (i) in subparagraph (F), by striking “;
17 and” and inserting a semicolon;

18 (ii) by redesignating subparagraph
19 (G) as subparagraph (H); and

20 (iii) by inserting after subparagraph
21 (F) the following:

22 “(G) the certification required under sec-
23 tion 402(j)(4)(B) of the Public Health Service
24 Act (which shall not be considered an element
25 of such application); and”.

1 (E) HUMANITARIAN DEVICE EXEMP-
2 TION.—Section 520(m)(2) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
4 amended in the first sentence in the matter fol-
5 lowing subparagraph (C), by inserting at the
6 end before the period “and such application
7 shall include the certification required under
8 section 402(j)(4)(B) of the Public Health Serv-
9 ice Act (which shall not be considered an ele-
10 ment of such application)”.

11 (c) PREEMPTION.—

12 (1) IN GENERAL.—No State or political subdivi-
13 sion of a State may establish or continue in effect
14 any requirement for the registration of clinical trials
15 or for the inclusion of information relating to the re-
16 sults of clinical trials in a database.

17 (2) RULE OF CONSTRUCTION.—The fact of sub-
18 mission of clinical trial information, if submitted in
19 compliance with subsection (i) and (j) of section 402
20 of the Public Health Service Act (as amended by
21 this section), that relates to a use of a drug or de-
22 vice not included in the official labeling of the ap-
23 proved drug or device shall not be construed by the
24 Secretary or in any administrative or judicial pro-
25 ceeding, as evidence of a new intended use of the

1 drug or device that is different from the intended
2 use of the drug or device set forth in the official la-
3 beling of the drug or device. The availability of clin-
4 ical trial information through the data bank under
5 such subsections (i) and (j), if submitted in compli-
6 ance with such subsections, shall not be considered
7 as labeling, adulteration, or misbranding of the drug
8 or device under the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 301 et seq.).

10 (d) TRANSITION RULE; EFFECTIVE DATE OF FUND-
11 ING RESTRICTIONS.—

12 (1) TRANSITION RULE FOR CLINICAL TRIALS
13 INITIATED PRIOR TO EXPANSION OF REGISTRY DATA
14 BANK.—The responsible party (as defined in para-
15 graph (1) of section 402(j) of the Public Health
16 Service Act (as added by this section)) for an appli-
17 cable drug clinical trial or applicable device clinical
18 trial (as defined under such paragraph (1)) that is
19 initiated after the date of enactment of this subtitle
20 and before the effective date of the regulations pro-
21 mulgated under paragraph (2) of such section
22 402(j), shall submit required clinical trial informa-
23 tion under such section not later than 120 days
24 after such effective date.

1 (2) FUNDING RESTRICTIONS.—Subparagraph
2 (A) of paragraph (4) of such section 402(j) shall
3 take effect 210 days after the effective date of the
4 regulations promulgated under paragraph (2) of
5 such section 402(j).

6 (e) EFFECTIVE DATE.—

7 (1) IN GENERAL.—Beginning 90 days after the
8 date of enactment of this title, the responsible party
9 for an applicable drug clinical trial or an applicable
10 device clinical trial (as that term is defined in such
11 section 402(j)) that is initiated after the date of en-
12 actment of this title and before the effective date of
13 the regulations issued under subparagraph (A) of
14 paragraph (2) of such subsection, shall submit clin-
15 ical trial information under such paragraph (2).

16 (2) RULEMAKING.—

17 (A) IN GENERAL.—Except as provided in
18 subparagraph (B), subsection (c)(1) shall be-
19 come effective on the date on which the regula-
20 tion promulgated pursuant to section
21 402(j)(3)(C)(i) of the Public Health Service
22 Act, as added by this section, becomes effective.

23 (B) EXCEPTION.—Subsection (c)(1) shall
24 apply with respect to any clinical trial for which
25 the registry data bank includes links to results

1 information, as provided for under section
 2 402(j)(3)(A) of such Act, as added by this sec-
 3 tion.

4 **Subtitle D—Conflicts of Interest**

5 **SEC. 241. CONFLICTS OF INTEREST.**

6 (a) IN GENERAL.—Subchapter A of chapter VII of
 7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
 8 et seq.) is amended by inserting at the end the following:

9 **“SEC. 712. CONFLICTS OF INTEREST.**

10 “(a) DEFINITIONS.—For purposes of this section:

11 “(1) ADVISORY COMMITTEE.—The term ‘advi-
 12 sory committee’ means an advisory committee under
 13 the Federal Advisory Committee Act that provides
 14 advice or recommendations to the Secretary regard-
 15 ing activities of the Food and Drug Administration.

16 “(2) FINANCIAL INTEREST.—The term ‘finan-
 17 cial interest’ means a financial interest under section
 18 208(a) of title 18, United States Code.

19 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

20 “(1) RECRUITMENT.—

21 “(A) IN GENERAL.—Given the importance
 22 of advisory committees to the review process at
 23 the Food and Drug Administration, the Sec-
 24 retary shall carry out informational and recruit-
 25 ment activities for purposes of recruiting indi-

1 viduals to serve as advisory committee mem-
2 bers. The Secretary shall seek input from pro-
3 fessional medical and scientific societies to de-
4 termine the most effective informational and re-
5 cruitment activities. The Secretary shall also
6 take into account the advisory committees with
7 the greatest number of vacancies.

8 “(B) RECRUITMENT ACTIVITIES.—The re-
9 cruitment activities under subparagraph (A)
10 may include—

11 “(i) advertising the process for becom-
12 ing an advisory committee member at med-
13 ical and scientific society conferences;

14 “(ii) making widely available, includ-
15 ing by using existing electronic commu-
16 nications channels, the contact information
17 for the Food and Drug Administration
18 point of contact regarding advisory com-
19 mittee nominations; and

20 “(iii) developing a method through
21 which an entity receiving National Insti-
22 tutes of Health funding can identify a per-
23 son who the Food and Drug Administra-
24 tion can contact regarding the nomination

1 of individuals to serve on advisory commit-
2 tees.

3 “(2) EVALUATION AND CRITERIA.—When con-
4 sidering a term appointment to an advisory com-
5 mittee, the Secretary shall review the expertise of
6 the individual and the financial disclosure report
7 filed by the individual pursuant to the Ethics in
8 Government Act of 1978 for each individual under
9 consideration for the appointment, so as to reduce
10 the likelihood that an appointed individual will later
11 require a written determination as referred to in sec-
12 tion 208(b)(1) of title 18, United States Code, a
13 written certification as referred to in section
14 208(b)(3) of title 18, United States Code, or a waiv-
15 er as referred to in subsection (c)(3) of this section
16 for service on the committee at a meeting of the
17 committee.

18 “(c) GRANTING AND DISCLOSURE OF WAIVERS.—

19 “(1) IN GENERAL.—Prior to a meeting of an
20 advisory committee regarding a ‘particular matter’
21 (as that term is used in section 208 of title 18,
22 United States Code), each member of the committee
23 who is a full-time Government employee or special
24 Government employee shall disclose to the Secretary

1 financial interests in accordance with subsection (b)
2 of such section 208.

3 “(2) FINANCIAL INTEREST OF ADVISORY COM-
4 MITTEE MEMBER OR FAMILY MEMBER.—No member
5 of an advisory committee may vote with respect to
6 any matter considered by the advisory committee if
7 such member (or an immediate family member of
8 such member) has a financial interest that could be
9 affected by the advice given to the Secretary with re-
10 spect to such matter, excluding interests exempted
11 in regulations issued by the Director of the Office of
12 Government Ethics as too remote or inconsequential
13 to affect the integrity of the services of the Govern-
14 ment officers or employees to which such regulations
15 apply.

16 “(3) WAIVER.—The Secretary may grant a
17 waiver of the prohibition in paragraph (2) if such
18 waiver is necessary to afford the advisory committee
19 essential expertise.

20 “(4) LIMITATION.—The Secretary may not
21 grant a waiver under paragraph (3) for a member
22 of an advisory committee when the member’s own
23 scientific work is involved.

1 “(5) DISCLOSURE OF WAIVER.—Notwith-
2 standing section 107(a)(2) of the Ethics in Govern-
3 ment Act (5 U.S.C. App.), the following shall apply:

4 “(A) 15 OR MORE DAYS IN ADVANCE.—As
5 soon as practicable, but in no case later than
6 15 days prior to a meeting of an advisory com-
7 mittee to which a written determination as re-
8 ferred to in section 208(b)(1) of title 18, United
9 States Code, a written certification as referred
10 to in section 208(b)(3) of title 18, United
11 States Code, or a waiver as referred to in para-
12 graph (3) applies, the Secretary shall disclose
13 (other than information exempted from disclo-
14 sure under section 552 of title 5, United States
15 Code, and section 552a of title 5, United States
16 Code (popularly known as the Freedom of In-
17 formation Act and the Privacy Act of 1974, re-
18 spectively)) on the Internet website of the Food
19 and Drug Administration—

20 “(i) the type, nature, and magnitude
21 of the financial interests of the advisory
22 committee member to which such deter-
23 mination, certification, or waiver applies;
24 and

1 “(ii) the reasons of the Secretary for
2 such determination, certification, or waiv-
3 er.

4 “(B) LESS THAN 30 DAYS IN ADVANCE.—
5 In the case of a financial interest that becomes
6 known to the Secretary less than 30 days prior
7 to a meeting of an advisory committee to which
8 a written determination as referred to in section
9 208(b)(1) of title 18, United States Code, a
10 written certification as referred to in section
11 208(b)(3) of title 18, United States Code, or a
12 waiver as referred to in paragraph (3) applies,
13 the Secretary shall disclose (other than infor-
14 mation exempted from disclosure under section
15 552 of title 5, United States Code, and section
16 552a of title 5, United States Code) on the
17 Internet website of the Food and Drug Admin-
18 istration, the information described in clauses
19 (i) and (ii) of subparagraph (A) as soon as
20 practicable after the Secretary makes such de-
21 termination, certification, or waiver, but in no
22 case later than the date of such meeting.

23 “(d) PUBLIC RECORD.—The Secretary shall ensure
24 that the public record and transcript of each meeting of
25 an advisory committee includes the disclosure required

1 under subsection (c)(5) (other than information exempted
2 from disclosure under section 552 of title 5, United States
3 Code, and section 552a of title 5, United States Code).

4 “(e) ANNUAL REPORT.—Not later than February 1
5 of each year, the Secretary shall submit to the Inspector
6 General of the Department of Health and Human Serv-
7 ices, the Committee on Appropriations and the Committee
8 on Health, Education, Labor, and Pensions of the Senate,
9 and the Committee on Appropriations and the Committee
10 on Energy and Commerce of the House of Representa-
11 tives, a report that describes—

12 “(1) with respect to the fiscal year that ended
13 on September 30 of the previous year, the number
14 of vacancies on each advisory committee, the number
15 of nominees received for each committee, and the
16 number of such nominees willing to serve;

17 “(2) with respect to such year, the aggregate
18 number of disclosures required under subsection
19 (c)(5) for each meeting of each advisory committee
20 and the percentage of individuals to whom such dis-
21 closures did not apply who served on such committee
22 for each such meeting;

23 “(3) with respect to such year, the number of
24 times the disclosures required under subsection

1 (c)(5) occurred under subparagraph (B) of such sub-
2 section; and

3 “(4) how the Secretary plans to reduce the
4 number of vacancies reported under paragraph (1)
5 during the fiscal year following such year, and mech-
6 anisms to encourage the nomination of individuals
7 for service on an advisory committee, including those
8 who are classified by the Food and Drug Adminis-
9 tration as academicians or practitioners.

10 “(f) PERIODIC REVIEW OF GUIDANCE.—Not less
11 than once every 5 years, the Secretary shall review guid-
12 ance of the Food and Drug Administration regarding con-
13 flict of interest waiver determinations with respect to advi-
14 sory committees and update such guidance as necessary.”.

15 (b) CONFORMING AMENDMENT.—Section 505(n) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355(n)) is amended by—

18 (1) striking paragraph (4); and

19 (2) redesignating paragraphs (5), (6), (7), and
20 (8) as paragraphs (4), (5), (6), and (7), respectively.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall take effect on October 1, 2007.

Subtitle E—Other Drug Safety Provisions

SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

“(q) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

“(1) IN GENERAL.—

“(A) PUBLICATION.—The Commissioner shall—

“(i) not later than 9 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

“(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

1 “(B) NOTIFICATION.—The Commissioner
2 shall notify relevant Federal agencies, including
3 the Centers for Medicare & Medicaid Services
4 and the Federal Trade Commission, any time
5 the Commissioner updates the information de-
6 scribed in subparagraph (A).

7 “(2) INCLUSION.—The Commissioner shall in-
8 clude in the list described in paragraph (1) each au-
9 thorized generic drug included in an annual report
10 submitted to the Secretary by the sponsor of a listed
11 drug after January 1, 1999.

12 “(3) AUTHORIZED GENERIC DRUG.—In this
13 section, the term ‘authorized generic drug’ means a
14 listed drug (as that term is used in subsection (j))
15 that—

16 “(A) has been approved under subsection
17 (c); and

18 “(B) is marketed, sold, or distributed di-
19 rectly or indirectly to retail class of trade under
20 a different labeling, packaging (other than re-
21 packaging as the listed drug in blister packs,
22 unit doses, or similar packaging for use in insti-
23 tutions), product code, labeler code, trade name,
24 or trade mark than the listed drug.”.

1 **SEC. 252. MEDICAL MARIJUANA.**

2 The Secretary shall require that State-legalized med-
3 ical marijuana be subject to the full regulatory require-
4 ments of the Food and Drug Administration, including a
5 risk evaluation and mitigation strategy and all other re-
6 quirements and penalties of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 301 et seq.) regarding safe and
8 effective reviews, approval, sale, marketing, and use of
9 pharmaceuticals.

10 **Subtitle F—Antibiotic Access and**
11 **Innovation**

12 **SEC. 261. INCENTIVES FOR THE DEVELOPMENT OF, AND**
13 **ACCESS TO, CERTAIN ANTIBIOTICS.**

14 (a) IN GENERAL.—Section 505 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by
16 this Act, is further amended by adding at the end the fol-
17 lowing:

18 “(s) ANTIBIOTIC DRUGS SUBMITTED BEFORE NO-
19 VEMBER 21, 1997.—

20 “(1) ANTIBIOTIC DRUGS APPROVED BEFORE
21 NOVEMBER 21, 1997.—

22 “(A) IN GENERAL.—Notwithstanding any
23 provision of the Food and Drug Administration
24 Modernization Act of 1997 or any other provi-
25 sion of law, a sponsor of a drug that is the sub-
26 ject of an application described in subparagraph

(B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

“(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

“(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

“(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

“(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

“(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration

1 Modernization Act of 1997 or any other provi-
2 sion of law, a sponsor of a drug that is the sub-
3 ject of an application described in subparagraph
4 (B)(i) may elect to be eligible for, with respect
5 to the drug—

6 “(i)(I) the 3-year exclusivity period re-
7 ferred to under clauses (iii) and (iv) of
8 subsection (c)(3)(E) and under clauses (iii)
9 and (iv) of subsection (j)(5)(F), subject to
10 the requirements of such clauses, as appli-
11 cable; and

12 “(II) the 5-year exclusivity period re-
13 ferred to under clause (ii) of subsection
14 (c)(3)(E) and under clause (ii) of sub-
15 section (j)(5)(F), subject to the require-
16 ments of such clauses, as applicable; or

17 “(ii) a patent term extension under
18 section 156 of title 35, United States
19 Code, subject to the requirements of such
20 section.

21 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
22 SCRIBED.—

23 “(i) APPLICATION.—An application
24 described in this clause is an application
25 for marketing submitted under this section

1 after the date of enactment of this sub-
2 section in which the drug that is the sub-
3 ject of the application contains an anti-
4 biotic drug described in clause (ii).

5 “(ii) ANTIBIOTIC DRUG.—An anti-
6 biotic drug described in this clause is an
7 antibiotic drug that was the subject of 1 or
8 more applications received by the Secretary
9 under section 507 of this Act (as in effect
10 before November 21, 1997), none of which
11 was approved by the Secretary under such
12 section.

13 “(3) LIMITATIONS.—

14 “(A) EXCLUSIVITIES AND EXTENSIONS.—
15 Paragraphs (1)(A) and (2)(A) shall not be con-
16 strued to entitle a drug that is the subject of
17 an approved application described in subpara-
18 graphs (1)(B)(i) or (2)(B)(i), as applicable, to
19 any market exclusivities or patent extensions
20 other than those exclusivities or extensions de-
21 scribed in paragraph (1)(A) or (2)(A).

22 “(B) CONDITIONS OF USE.—Paragraphs
23 (1)(A) and (2)(A)(i) shall not apply to any con-
24 dition of use for which the drug referred to in
25 subparagraph (1)(B)(i) or (2)(B)(i), as applica-

1 ble, was approved before the date of enactment
2 of this subsection.

3 “(4) APPLICATION OF CERTAIN PROVISIONS.—
4 Notwithstanding section 125, or any other provision,
5 of the Food and Drug Administration Modernization
6 Act of 1997, or any other provision of law, and sub-
7 ject to the limitations in paragraphs (1), (2), and
8 (3), the provisions of the Drug Price Competition
9 and Patent Term Restoration Act of 1984 shall
10 apply to any drug subject to paragraph (1) or any
11 drug with respect to which an election is made under
12 paragraph (2)(A).”.

13 (b) TRANSITION RULE.—With respect to a patent
14 issued on or before the date of enactment of this Act, any
15 patent information required to be filed with the Secretary
16 under subsection (b)(1) or (c)(2) of section 505 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
18 to be listed on a drug to which subsection (s)(1) of such
19 section 505 (as added by this section) applies shall be filed
20 with such Secretary not later than 60 days after the date
21 of enactment of this Act.

22 **SEC. 262. ANTIBIOTICS AS ORPHAN PRODUCTS.**

23 (a) PUBLIC MEETING.—The Commissioner of Food
24 and Drugs shall convene a public meeting and, if appro-
25 priate, issue guidance, regarding which serious and life-

1 threatening infectious diseases, such as diseases due to
 2 gram-negative bacteria and other diseases due to anti-
 3 biotic-resistant bacteria, potentially qualify for available
 4 grants and contracts under subsection (a) of section 5 of
 5 the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incen-
 6 tives for development.

7 (b) GRANTS AND CONTRACTS FOR THE DEVELOP-
 8 MENT OF ORPHAN DRUGS.—Subsection (c) of section 5
 9 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended
 10 to read as follows:

11 “(c) For grants and contracts under subsection (a)
 12 there are authorized to be appropriated—

13 “(1) such sums as already have been appro-
 14 priated for fiscal year 2007; and

15 “(2) \$35,000,000 for each of fiscal years 2008
 16 through 2012.”.

17 **SEC. 263. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE**
 18 **CONCENTRATIONS OF ANTIMICROBIALS.**

19 (a) DEFINITION.—In this section, the term “clinically
 20 susceptible concentrations” means specific values which
 21 characterize bacteria as clinically susceptible, inter-
 22 mediate, or resistant to the drug (or drugs) tested.

23 (b) IDENTIFICATION.—The Secretary of Health and
 24 Human Services (referred to in this section as the “Sec-
 25 retary”), through the Commissioner of Food and Drugs,

1 shall identify and periodically update clinically susceptible
2 concentrations.

3 (c) PUBLIC AVAILABILITY.—The Secretary, through
4 the Commissioner of Food and Drugs, shall make such
5 clinically susceptible concentrations publicly available
6 within 30 days of the date of identification and any update
7 under this section.

8 (d) EFFECT.—Nothing in this section shall be con-
9 strued to restrict, in any manner, the prescribing of anti-
10 biotics by physicians, or to limit the practice of medicine,
11 including for diseases such as Lyme and tick-borne dis-
12 eases.

13 **SEC. 264. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING**
14 **SINGLE ENANTIOMERS.**

15 Section 505 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S. C. 355), as amended by this subtitle, is
17 amended by adding at the end the following:

18 “(t) CERTAIN DRUGS CONTAINING SINGLE
19 ENANTIOMERS.—

20 “(1) IN GENERAL.—For purposes of sub-
21 sections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an applica-
22 tion is submitted under subsection (b) for a non-ra-
23 cemic drug containing as an active ingredient a sin-
24 gle enantiomer that is contained in a racemic drug
25 approved in another application under subsection

1 (b), the applicant may, in the application for such
2 non-racemic drug, elect to have the single
3 enantiomer not be considered the same active ingre-
4 dient as that contained in the approved racemic
5 drug, if—

6 “(A)(i) the single enantiomer has not been
7 previously approved except in the approved ra-
8 cemic drug; and

9 “(ii) the application submitted under sub-
10 section (b) for such non-racemic drug—

11 “(I) includes full reports of new clin-
12 ical investigations (other than bio-
13 availability studies)—

14 “(aa) necessary for the approval
15 of the application under subsections
16 (c) and (d); and

17 “(bb) conducted or sponsored by
18 the applicant; and

19 “(II) does not rely on any investiga-
20 tions that are part of an application sub-
21 mitted under subsection (b) for approval of
22 the approved racemic drug; and

23 “(B) the application submitted under sub-
24 section (b) for such non-racemic drug is not
25 submitted for approval of a condition of use—

1 “(i) in a therapeutic category in which
2 the approved racemic drug has been ap-
3 proved; or

4 “(ii) for which any other enantiomer
5 of the racemic drug has been approved.

6 “(2) LIMITATION.—

7 “(A) NO APPROVAL IN CERTAIN THERA-
8 PEUTIC CATEGORIES.—Until the date that is 10
9 years after the date of approval of a non-race-
10 mic drug described in paragraph (1) and with
11 respect to which the applicant has made the
12 election provided for by such paragraph, the
13 Secretary shall not approve such non-racemic
14 drug for any condition of use in the therapeutic
15 category in which the racemic drug has been
16 approved.

17 “(B) LABELING.—If applicable, the label-
18 ing of a non-racemic drug described in para-
19 graph (1) and with respect to which the appli-
20 cant has made the election provided for by such
21 paragraph shall include a statement that the
22 non-racemic drug is not approved, and has not
23 been shown to be safe and effective, for any
24 condition of use of the racemic drug.

25 “(3) DEFINITION.—

1 “(A) IN GENERAL.—For purposes of this
 2 subsection, the term ‘therapeutic category’
 3 means a therapeutic category identified in the
 4 list developed by the United States Pharma-
 5 copeia pursuant to section 1860D–
 6 4(b)(3)(C)(ii) of the Social Security Act and as
 7 in effect on the date of enactment of this sub-
 8 section.

9 “(B) PUBLICATION BY SECRETARY.—The
 10 Secretary shall publish the list described in sub-
 11 paragraph (A) and may amend such list by reg-
 12 ulation.

13 “(4) AVAILABILITY.—The election referred to
 14 in paragraph (1) may be made only in an application
 15 that is submitted to the Secretary after the date of
 16 enactment of this subsection and before October 1,
 17 2012.”.

18 **SEC. 265. REPORT.**

19 Not later than January 1, 2012, the Comptroller
 20 General of the United States shall submit a report to the
 21 Committee on Health, Education, Labor, and Pensions of
 22 the Senate and the Committee on Energy and Commerce
 23 of the House of Representatives that examines whether
 24 and how this subtitle has—

- 1 (1) encouraged the development of new anti-
 2 biotics and other drugs; and
- 3 (2) prevented or delayed timely generic drug
 4 entry into the market.

5 **TITLE III—MEDICAL DEVICES**

6 **SEC. 300. REFERENCES.**

7 Except as otherwise specified, whenever in this title
 8 an amendment is expressed in terms of an amendment to
 9 a section or other provision, the reference shall be consid-
 10 ered to be made to a section or other provision of the Fed-
 11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
 12 seq.).

13 **Subtitle A—Device User Fees**

14 **SEC. 301. SHORT TITLE.**

15 This subtitle may be cited as the “Medical Device
 16 User Fee Amendments of 2007”.

17 **SEC. 302. DEVICE FEES.**

18 Section 737 (21 U.S.C. 379i) is amended—

- 19 (1) by striking the section designation and all
 20 that follows through “For purposes of this sub-
 21 chapter” and inserting the following:

22 **“SEC. 737. DEVICE FEES.**

23 “(a) PURPOSE.—It is the purpose of this part that
 24 the fees authorized under this part be dedicated toward
 25 expediting the process for the review of device applications

1 and for assuring the safety and effectiveness of devices,
2 as set forth in the goals identified for purposes of this
3 part in the letters from the Secretary to the Chairman
4 of the Committee on Health, Education, Labor, and Pen-
5 sions of the Senate and the Chairman of the Committee
6 on Energy and Commerce of the House of Representa-
7 tives, as set forth in the Congressional Record.

8 “(b) REPORTS.—

9 “(1) PERFORMANCE REPORT.—For fiscal years
10 2008 through 2012, not later than 120 days after
11 the end of each fiscal year during which fees are col-
12 lected under this part, the Secretary shall prepare
13 and submit to the Committee on Health, Education,
14 Labor, and Pensions of the Senate and the Com-
15 mittee on Energy and Commerce of the House of
16 Representatives, a report concerning the progress of
17 the Food and Drug Administration in achieving the
18 goals identified in the letters described in subsection
19 (a) during such fiscal year and the future plans of
20 the Food and Drug Administration for meeting the
21 goals. The report for a fiscal year shall include infor-
22 mation on all previous cohorts for which the Sec-
23 retary has not given a complete response on all de-
24 vice premarket applications, supplements, and pre-
25 market notifications in the cohort.

1 “(2) FISCAL REPORT.—For fiscal years 2008
2 through 2012, not later than 120 days after the end
3 of each fiscal year during which fees are collected
4 under this part, the Secretary shall prepare and sub-
5 mit to the Committee on Health, Education, Labor,
6 and Pensions of the Senate and the Committee on
7 Energy and Commerce of the House of Representa-
8 tives, a report on the implementation of the author-
9 ity for such fees during such fiscal year and the use,
10 by the Food and Drug Administration, of the fees
11 collected during such fiscal year for which the report
12 is made.

13 “(3) PUBLIC AVAILABILITY.—The Secretary
14 shall make the reports required under paragraphs
15 (1) and (2) available to the public on the Internet
16 website of the Food and Drug Administration.

17 “(c) REAUTHORIZATION.—

18 “(1) CONSULTATION.—In developing rec-
19 ommendations to present to Congress with respect to
20 the goals, and plans for meeting the goals, for the
21 process for the review of device applications for the
22 first 5 fiscal years after fiscal year 2012, and for the
23 reauthorization of this part for such fiscal years, the
24 Secretary shall consult with—

1 “(A) the Committee on Energy and Com-
2 merce of the House of Representatives;

3 “(B) the Committee on Health, Education,
4 Labor, and Pensions of the Senate;

5 “(C) scientific and academic experts;

6 “(D) health care professionals;

7 “(E) representatives of patient and con-
8 sumer advocacy groups; and

9 “(F) the regulated industry.

10 “(2) PUBLIC REVIEW OF RECOMMENDA-
11 TIONS.—After negotiations with the regulated indus-
12 try, the Secretary shall—

13 “(A) present the recommendations devel-
14 oped under paragraph (1) to the Congressional
15 committees specified in such paragraph;

16 “(B) publish such recommendations in the
17 Federal Register;

18 “(C) provide for a period of 30 days for
19 the public to provide written comments on such
20 recommendations;

21 “(D) hold a meeting at which the public
22 may present its views on such recommenda-
23 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2012, the Secretary
6 shall transmit to Congress the revised recommenda-
7 tions under paragraph (2), a summary of the views
8 and comments received under such paragraph, and
9 any changes made to the recommendations in re-
10 sponse to such views and comments.

11 “(d) DEFINITIONS.—For purposes of this part:”;

12 (2) by redesignating paragraphs (5), (6), (7),
13 and (8), as paragraphs (7), (8), (9), and (11), re-
14 spectively;

15 (3) in paragraph (4)—

16 (A) in subparagraph (A), by striking “or
17 an efficacy supplement,” and inserting “an effi-
18 cacy supplement, or a 30-day notice,”; and

19 (B) by adding at the end the following:

20 “(F) The term ‘30-day notice’ means a supple-
21 ment to an approved premarket application or pre-
22 market report under section 515 that is limited to
23 a request to make modifications to manufacturing
24 procedures or methods of manufacture affecting the
25 safety and effectiveness of the device.”;

1 (4) by inserting after paragraph (4) the fol-
2 lowing:

3 “(5) The term ‘request for classification infor-
4 mation’ means a request made under section 513(g)
5 for information respecting the class in which a de-
6 vice has been classified or the requirements applica-
7 ble to a device.

8 “(6) The term ‘annual fee for periodic reporting
9 concerning a class III device’ means the fee associ-
10 ated with reports imposed by a premarket applica-
11 tion approval order (as described in section
12 814.82(a)(7) of title 21, Code of Federal Regula-
13 tions), usually referred to as ‘annual reports.’”;

14 (5) in paragraph (9), as redesignated by para-
15 graph (2)—

16 (A) by striking “April of” and inserting
17 “October of”; and

18 (B) by striking “April 2002” and inserting
19 “October 2001”;

20 (6) by inserting after paragraph (9), as redesign-
21 ated by paragraph (2), the following:

22 “(10) The term ‘person’ includes an affiliate of
23 such person.”; and

24 (7) by adding at the end the following:

1 “(12) The term ‘establishment subject to a reg-
2 istration fee’ means an establishment required to
3 register with the Secretary under section 510 at
4 which any of the following types of activities are
5 conducted:

6 “(A) MANUFACTURER.—An establishment
7 that makes by any means any article that is a
8 device including an establishment that sterilizes
9 or otherwise makes such article for or on behalf
10 of a specification developer or any other person.

11 “(B) SINGLE-USE DEVICE REPROC-
12 ESSOR.—An establishment that performs manu-
13 facturing operations on a single-use device that
14 has previously been used on a patient.

15 “(C) SPECIFICATION DEVELOPER.—An es-
16 tablishment that develops specifications for a
17 device that is distributed under the establish-
18 ment’s name but that performs no manufac-
19 turing, including establishments that, in addi-
20 tion to developing specifications, arrange for the
21 manufacturing of devices labeled with another
22 establishment’s name by a contract manufac-
23 turer.

24 “(13) The term ‘establishment registration fee’
25 means a fee assessed under section 738(a)(3) for the

1 registration of an establishment subject to a reg-
 2 istration fee.

3 “(e) SUNSET.—This part shall cease to be effective
 4 on October 1, 2012, except that subsection (b) with re-
 5 spect to reports shall cease to be effective January 31,
 6 2013.”.

7 **SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

8 Section 738 (21 U.S.C. 379j) is amended—

9 (1) in subsection (a)—

10 (A) in paragraph (2)—

11 (i) in the header, by inserting “, AND
 12 ANNUAL FEE FOR PERIODIC REPORTING
 13 CONCERNING A CLASS III DEVICE” after
 14 “FEE”;

15 (ii) in subparagraph (A)—

16 (I) in clause (iii), by inserting
 17 “75 percent of” after “a fee equal
 18 to”;

19 (II) in clause (iv), by striking
 20 “21.5” and inserting “15”;

21 (III) in clause (v), by striking
 22 “7.2” and inserting “7”;

23 (IV) by redesignating clauses (vi)
 24 and (vii) as clauses (vii) and (viii), re-
 25 spectively;

1 (V) by inserting after clause (v)
2 the following:

3 “(vi) For a 30-day notice, a fee equal
4 to 1.6 percent of the fee that applies under
5 clause (i).”;

6 (VI) in clause (viii), as redesign-
7 nated by subclause (IV)—

8 (aa) by striking “1.42” and
9 inserting “1.84”; and

10 (bb) by striking “, subject to
11 any adjustment under subsection
12 (e)(2)(C)(ii)”;

13 (VII) by adding at the end the
14 following:

15 “(ix) For a request for classification
16 information, a fee equal to 1.35 percent of
17 the fee that applies under clause (i).

18 “(x) For periodic reporting concerning
19 a class III device, the annual fee shall be
20 equal to 3.5 percent of the fee that applies
21 under clause (i).”;

22 (iii) in subparagraph (C)—

23 (I) in the first sentence—

24 (aa) by striking “or”; and

1 (bb) by striking “except
2 that” and all that follows
3 through the period and inserting
4 “, 30-day notice, request for clas-
5 sification information, or periodic
6 report concerning a class III de-
7 vice.”; and
8 (II) by striking the third sen-
9 tence; and
10 (iv) in subparagraph (D)—
11 (I) in clause (iii), by striking the
12 last two sentences; and
13 (II) by adding at the end the fol-
14 lowing:
15 “(iv) MODULAR APPLICATION WITH-
16 DRAWN BEFORE FIRST ACTION.—The Sec-
17 retary shall refund 75 percent of the appli-
18 cation fee paid for a modular application
19 submitted under section 515(c)(4) that is
20 withdrawn before a second module is sub-
21 mitted and before a first action on the first
22 module. If the modular application is with-
23 drawn after a second or subsequent module
24 is submitted but before any first action,
25 the Secretary may return a portion of the

1 fee. The amount of refund, if any, shall be
 2 based on the level of effort already ex-
 3 pended on the review of the modules sub-
 4 mitted.

5 “(v) SOLE DISCRETION TO REFUND.—

6 The Secretary shall have sole discretion to
 7 refund a fee or portion of the fee under
 8 this subparagraph. A determination by the
 9 Secretary concerning a refund under this
 10 paragraph shall not be reviewable.”; and

11 (B) by adding at the end the following:

12 “(3) ANNUAL ESTABLISHMENT REGISTRATION
 13 FEE.—

14 “(A) IN GENERAL.—Except as provided in
 15 subparagraph (B), each establishment subject
 16 to a registration fee shall be subject to a fee for
 17 each initial or annual registration beginning
 18 with its registration for fiscal year 2008.

19 “(B) EXCEPTION FOR FEDERAL OR STATE
 20 GOVERNMENT ESTABLISHMENT.—No fee shall
 21 be required under subparagraph (A) for an es-
 22 tablishment operated by a Federal or State gov-
 23 ernment entity unless a device manufactured by
 24 the establishment is to be distributed commer-
 25 cially.

1 “(C) PAYMENT.—The annual establish-
 2 ment registration fee shall be due once each fis-
 3 cal year, upon the initial registration of the es-
 4 tablishment or upon the annual registration
 5 under section 510.”;

6 (2) by striking subsection (b) and inserting the
 7 following:

8 “(b) FEE AMOUNTS.—Except as provided in sub-
 9 sections (c), (d), and (e), the fees under subsection (a)
 10 shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Ap- plication	\$185,000	\$200,725	\$217,787	\$236,298	\$256,384
Establishment Registration Fee	\$1,706	\$1,851	\$2,008	\$2,179	\$2,364”;

11 (3) in subsection (c)—

12 (A) in the heading, by striking “Annual
 13 Fee Setting.—” and inserting “ANNUAL FEE
 14 SETTING.—”;

15 (B) in paragraph (1), by striking the sec-
 16 ond sentence;

17 (C) by redesignating paragraphs (2) and
 18 (3) as paragraphs (3) and (4), respectively;

1 (D) by inserting after paragraph (1) the
2 following:

3 “(2) ADJUSTMENT OF ANNUAL ESTABLISH-
4 MENT REGISTRATION FEE.—

5 “(A) IN GENERAL.—When setting the fees
6 for fiscal year 2010, the Secretary may increase
7 the establishment registration fee specified in
8 subsection (b) only if the Secretary estimates
9 that the number of establishments submitting
10 fees for fiscal year 2009 is less than 12,250.
11 The percent increase shall be the percent by
12 which the estimate of establishments submitting
13 fees in fiscal year 2009 is less than 12,750, but
14 in no case shall the percent increase be more
15 than 8.5 percent over the amount for such fee
16 specified in subsection (b) for fiscal year 2010.
17 If the Secretary makes any adjustment to the
18 establishment registration fee for fiscal year
19 2010, then the establishment registration fee
20 for fiscal years 2011 and 2012 under sub-
21 section (b) shall be adjusted as follows: the fee
22 for fiscal year 2011 shall be equal to the ad-
23 justed fee for fiscal year 2010, increased by 8.5
24 percent, and the fee for fiscal year 2012 shall

1 be equal to the adjusted fee for fiscal year
2 2011, increased by 8.5 percent.

3 “(B) PUBLICATION IN THE FEDERAL REG-
4 ISTER.—The Secretary shall publish any deter-
5 mination with respect to any establishment reg-
6 istration fee adjustment made under subpara-
7 graph (A), and the rationale for such deter-
8 mination, in the Federal Register.”; and

9 (E) in paragraph (4)(A), as so redesign-
10 nated—

11 (i) by striking “For fiscal years 2006
12 and 2007, the” and inserting “The”; and

13 (ii) by striking “of fiscal year 2008”
14 and inserting “of the next fiscal year”;

15 (4) in subsection (d)—

16 (A) in paragraph (1), by striking “, part-
17 ners, and parent firms”;

18 (B) in paragraph (2)—

19 (i) in subparagraph (A), by striking “,
20 partners, and parent firms”;

21 (ii) in subparagraph (B)—

22 (I) by striking “An applicant
23 shall” and inserting the following:

24 “(i) IN GENERAL.—An applicant
25 shall”;

1 (II) by striking “The applicant
2 shall support” and inserting the fol-
3 lowing:

4 “(ii) FIRMS SUBMITTING TAX RE-
5 TURNS TO THE UNITED STATES INTERNAL
6 REVENUE SERVICE.—The applicant shall
7 support”;

8 (III) by striking “, partners, and
9 parent firms” both places the term
10 appears;

11 (IV) by striking “partners, or
12 parent firms, the” and inserting
13 “the”;

14 (V) by striking “, partners, or
15 parent firms, respectively”; and

16 (VI) by adding at the end the fol-
17 lowing:

18 “(iii) FIRMS NOT SUBMITTING TAX
19 RETURNS TO THE UNITED STATES INTER-
20 NAL REVENUE SERVICE.—The applicant
21 shall support its claim that it meets the
22 definition under subparagraph (A) by sub-
23 mission of the following:

24 “(I) A signed certification, in
25 such form as the Secretary may direct

1 through a notice published in the Fed-
2 eral Register, that the applicant meets
3 the criteria for a small business.

4 “(II) A certification, in English,
5 from the national taxing authority of
6 the country in which it is
7 headquartered. Such certification shall
8 provide the applicant’s gross receipts
9 and sales for the most recent year, in
10 both the local currency and in United
11 States dollars, the exchange rate used
12 in making this conversion to dollars,
13 and the dates during which these re-
14 cepts and sales were collected, and it
15 shall bear the official seal of the na-
16 tional taxing authority.

17 “(III) Identical certifications
18 shall be provided for each of the appli-
19 cant’s affiliates.

20 “(IV) A statement signed by the
21 head of the applicant or its chief fi-
22 nancial officer that it has submitted
23 certifications for all of its affiliates, or
24 that it had no affiliates, whichever is
25 applicable.”; and

1 (iii) in subparagraph (C)—

2 (I) by striking “reduced rate of”
3 and inserting “reduced rate of—”;
4 and

5 (II) by striking “38 percent” and
6 all that follows through the period and
7 inserting the following:

8 “(i) 25 percent of the fee established
9 under such subsection for a premarket ap-
10 plication, a premarket report, a supple-
11 ment, or a periodic report concerning a
12 class III device; and

13 “(ii) 50 percent of the fee established
14 under such subsection for a 30-day notice
15 or a request for classification informa-
16 tion.”;

17 (5) in subsection (e)—

18 (A) in paragraph (1), by striking “2004”
19 and inserting “2008”; and

20 (B) in paragraph (2)—

21 (i) in subparagraph (A), by striking “,
22 partners, and parent firms”;

23 (ii) by striking subparagraph (B) and
24 inserting the following:

25 “(B) EVIDENCE OF QUALIFICATION.—

1 “(i) IN GENERAL.—An applicant shall
2 pay the higher fees established by the Sec-
3 retary each year unless the applicant sub-
4 mits evidence that it qualifies for the lower
5 fee rate.

6 “(ii) FIRMS SUBMITTING TAX RE-
7 TURNS TO THE UNITED STATES INTERNAL
8 REVENUE SERVICE.—The applicant shall
9 support its claim that it meets the defini-
10 tion under subparagraph (A) by submis-
11 sion of a copy of its most recent Federal
12 income tax return for a taxable year, and
13 a copy of such returns of its affiliates,
14 which show an amount of gross sales or re-
15 ceipts that is less than the maximum es-
16 tablished in subparagraph (A). The appli-
17 cant, and each of such affiliates, shall cer-
18 tify that the information provided is a true
19 and accurate copy of the actual tax forms
20 they submitted to the Internal Revenue
21 Service. If no tax forms are submitted for
22 affiliates, the applicant shall certify that
23 the applicant has no affiliates.

24 “(iii) FIRMS NOT SUBMITTING TAX
25 RETURNS TO THE UNITED STATES INTER-

1 NAL REVENUE SERVICE.—The applicant
2 shall support its claim that it meets the
3 definition under subparagraph (A) by sub-
4 mission of the following:

5 “(I) A signed certification, in
6 such form as the Secretary may direct
7 through a notice published in the Fed-
8 eral Register, that the applicant meets
9 the criteria for a small business.

10 “(II) A certification, in English,
11 from the national taxing authority of
12 the country in which it is
13 headquartered. Such certification shall
14 provide the applicant’s gross receipts
15 and sales for the most recent year, in
16 both the local currency and in United
17 States dollars, and the exchange rate
18 used in making such conversion to
19 dollars, and the dates during which
20 such receipts and sales were collected,
21 and it shall bear the official seal of
22 the national taxing authority.

23 “(III) Identical certifications
24 shall be provided for each of the appli-
25 cant’s affiliates.

1 “(IV) A statement signed by the
2 head of the applicant or its chief fi-
3 nancial officer that it has submitted
4 certifications for all of its affiliates, or
5 that it had no affiliates, whichever is
6 applicable.”; and

7 (iii) by striking subparagraph (C) and
8 inserting the following:

9 “(C) REDUCED FEES.—For fiscal year
10 2008 and each subsequent fiscal year, where
11 the Secretary finds that the applicant involved
12 meets the definition under subparagraph (A),
13 the fee for a premarket notification submission
14 may be paid at 50 percent of the fee that ap-
15 plies under subsection (a)(2)(A)(viii) and as es-
16 tablished under subsection (c)(1).”;

17 (6) by striking subsection (f) and inserting the
18 following:

19 “(f) EFFECT OF FAILURE TO PAY FEES.—

20 “(1) IN GENERAL.—A premarket application,
21 premarket report, supplement, or premarket notifi-
22 cation submission, 30-day notice, request for classi-
23 fication information, or periodic report concerning a
24 class III device submitted by a person subject to fees
25 under paragraphs (2) and (3) of subsection (a) shall

1 be considered incomplete and shall not be accepted
2 by the Secretary until all fees owed by such person
3 have been paid.

4 “(2) REGISTRATION INFORMATION.—Registra-
5 tion information submitted by an establishment sub-
6 ject to a registration fee under subsection (a)(3)
7 shall be considered incomplete and shall not be ac-
8 cepted by the Secretary until the registration fee
9 owed for the establishment has been paid. Until the
10 fee is paid and the registration is complete, the es-
11 tablishment shall be deemed to have failed to reg-
12 ister in accordance with section 510.”;

13 (7) in subsection (g)—

14 (A) by striking paragraph (1) and insert-
15 ing the following:

16 “(1) PERFORMANCE GOALS; TERMINATION OF
17 PROGRAM.—With respect to the amount that, under
18 the salaries and expenses account of the Food and
19 Drug Administration, is appropriated for a fiscal
20 year for devices and radiological products, fees may
21 not be assessed under subsection (a) for the fiscal
22 year, and the Secretary is not expected to meet any
23 performance goals identified for the fiscal year, if—

24 “(A) the amount so appropriated for the
25 fiscal year, excluding the amount of fees appro-

1 priated for the fiscal year, is more than 1 per-
 2 cent less than \$205,720,000 multiplied by the
 3 adjustment factor applicable to such fiscal year;
 4 or

5 “(B) fees were not assessed under sub-
 6 section (a) for the previous fiscal year.”; and

7 (B) in paragraph (2), by striking “and
 8 premarket notification submissions, and” and
 9 inserting “premarket notification submissions,
 10 30-day notices, requests for classification infor-
 11 mation, periodic reports concerning a class III
 12 device, and establishment registrations”; and
 13 (8) in subsection (h), by striking paragraphs
 14 (3) and (4) and inserting the following:

15 “(3) AUTHORIZATION OF APPROPRIATIONS.—
 16 There are authorized to be appropriated for fees
 17 under this section—

18 “(A) \$48,431,000 for fiscal year 2008;

19 “(B) \$52,547,000 for fiscal year 2009;

20 “(C) \$57,014,000 for fiscal year 2010;

21 “(D) \$61,860,000 for fiscal year 2011;

22 and

23 “(E) \$67,118,000 for fiscal year 2012.

24 “(4) OFFSET.—If the cumulative amount of
 25 fees collected during fiscal years 2008, 2009, and

1 2010, added to the amount estimated to be collected
2 for fiscal year 2011 (which estimate shall be based
3 upon the amount of fees received by the Secretary
4 through June 30, 2011), exceeds the amount of fees
5 specified in aggregate in paragraph (3) for such 4
6 fiscal years, the aggregate amount in excess shall be
7 credited to the appropriation account of the Food
8 and Drug Administration as provided in paragraph
9 (1), and shall be subtracted from the amount of fees
10 that would otherwise be authorized to be collected
11 under this section pursuant to appropriation Acts
12 for fiscal year 2012.”.

13 **SEC. 304. SAVINGS CLAUSE.**

14 Notwithstanding section 107 of the Medical Device
15 User Fee and Modernization Act of 2002 (Public Law
16 107–250), and notwithstanding the amendments made by
17 this subtitle, part 3 of subchapter C of chapter VII of the
18 Federal Food, Drug, and Cosmetic Act, as in effect on
19 the day before the date of enactment of this subtitle, shall
20 continue to be in effect with respect to premarket applica-
21 tions, premarket reports, premarket notification submis-
22 sions, and supplements (as defined in such part as of such
23 day) that on or after October 1, 2002, but before October
24 1, 2007, were accepted by the Food and Drug Administra-
25 tion for filing with respect to assessing and collecting any

1 fee required by such part for a fiscal year prior to fiscal
2 year 2008.

3 **SEC. 305. EFFECTIVE DATE.**

4 The amendments made by this subtitle shall take ef-
5 fect on October 1, 2007.

6 **Subtitle B—Amendments Regard-**
7 **ing Regulation of Medical De-**
8 **vices**

9 **SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.**

10 Section 704(g) (21 U.S.C. 374(g)) is amended—

11 (1) in paragraph (1), by striking “Not later
12 than one year after the date of enactment of this
13 subsection, the Secretary” and inserting “The Sec-
14 retary”;

15 (2) in paragraph (2), by—

16 (A) striking “Not later than 180 days
17 after the date of enactment of this subsection,
18 the” and inserting “The Secretary”; and

19 (B) striking the fifth sentence;

20 (3) in paragraph (3), by adding at the end the
21 following:

22 “(F) Such person shall notify the Sec-
23 retary of any withdrawal, suspension, restric-
24 tion, or expiration of certificate of conformance
25 with the quality systems standard referred to in

1 paragraph (7) for any device establishment that
2 such person inspects under this subsection not
3 later than 30 days after such withdrawal, sus-
4 pension, restriction, or expiration.

5 “(G) Such person may conduct audits to
6 establish conformance with the quality systems
7 standard referred to in paragraph (7).”;

8 (4) by amending paragraph (6) to read as fol-
9 lows:

10 “(6)(A) Subject to subparagraphs (B) and (C), a de-
11 vice establishment is eligible for inspection by persons ac-
12 credited under paragraph (2) if the following conditions
13 are met:

14 “(i) The Secretary classified the results of the
15 most recent inspection of the establishment as ‘no
16 action indicated’ or ‘voluntary action indicated’.

17 “(ii) With respect to inspections of the estab-
18 lishment to be conducted by an accredited person,
19 the owner or operator of the establishment submits
20 to the Secretary a notice that—

21 “(I) provides the date of the last inspection
22 of the establishment by the Secretary and the
23 classification of that inspection;

1 “(II) states the intention of the owner or
2 operator to use an accredited person to conduct
3 inspections of the establishment;

4 “(III) identifies the particular accredited
5 person the owner or operator intends to select
6 to conduct such inspections; and

7 “(IV) includes a certification that, with re-
8 spect to the devices that are manufactured, pre-
9 pared, propagated, compounded, or processed in
10 the establishment—

11 “(aa) at least 1 of such devices is
12 marketed in the United States; and

13 “(bb) at least 1 of such devices is
14 marketed, or is intended to be marketed,
15 in 1 or more foreign countries, 1 of which
16 countries certifies, accredits, or otherwise
17 recognizes the person accredited under
18 paragraph (2) and identified under sub-
19 clause (III) as a person authorized to con-
20 duct inspections of device establishments.

21 “(B)(i) Except with respect to the requirement of
22 subparagraph (A)(i), a device establishment is deemed to
23 have clearance to participate in the program and to use
24 the accredited person identified in the notice under sub-
25 paragraph (A)(ii) for inspections of the establishment un-

1 less the Secretary, not later than 30 days after receiving
2 such notice, issues a response that—

3 “(I) denies clearance to participate as provided
4 under subparagraph (C); or

5 “(II) makes a request under clause (ii).

6 “(ii) The Secretary may request from the owner or
7 operator of a device establishment in response to the no-
8 tice under subparagraph (A)(ii) with respect to the estab-
9 lishment, or from the particular accredited person identi-
10 fied in such notice—

11 “(I) compliance data for the establishment in
12 accordance with clause (iii)(I); or

13 “(II) information concerning the relationship
14 between the owner or operator of the establishment
15 and the accredited person identified in such notice in
16 accordance with clause (iii)(II).

17 The owner or operator of the establishment, or such
18 accredited person, as the case may be, shall respond
19 to such a request not later than 60 days after receiv-
20 ing such request.

21 “(iii)(I) The compliance data to be submitted by the
22 owner or operation of a device establishment in response
23 to a request under clause (ii)(I) are data describing wheth-
24 er the quality controls of the establishment have been suf-
25 ficient for ensuring consistent compliance with current

1 good manufacturing practice within the meaning of section
2 501(h) and with other applicable provisions of this Act.
3 Such data shall include complete reports of inspectional
4 findings regarding good manufacturing practice or other
5 quality control audits that, during the preceding 2-year
6 period, were conducted at the establishment by persons
7 other than the owner or operator of the establishment, to-
8 gether with all other compliance data the Secretary deems
9 necessary. Data under the preceding sentence shall dem-
10 onstrate to the Secretary whether the establishment has
11 facilitated consistent compliance by promptly correcting
12 any compliance problems identified in such inspections.

13 “(II) A request to an accredited person under clause
14 (ii)(II) may not seek any information that is not required
15 to be maintained by such person in records under sub-
16 section (f)(1).

17 “(iv) A device establishment is deemed to have clear-
18 ance to participate in the program and to use the accred-
19 ited person identified in the notice under subparagraph
20 (A)(ii) for inspections of the establishment unless the Sec-
21 retary, not later than 60 days after receiving the informa-
22 tion requested under clause (ii), issues a response that de-
23 nies clearance to participate as provided under subpara-
24 graph (C).

1 “(C)(i) The Secretary may deny clearance to a device
2 establishment if the Secretary has evidence that the cer-
3 tification under subparagraph (A)(ii)(IV) is untrue and
4 the Secretary provides to the owner or operator of the es-
5 tablishment a statement summarizing such evidence.

6 “(ii) The Secretary may deny clearance to a device
7 establishment if the Secretary determines that the estab-
8 lishment has failed to demonstrate consistent compliance
9 for purposes of subparagraph (B)(iii)(I) and the Secretary
10 provides to the owner or operator of the establishment a
11 statement of the reasons for such determination.

12 “(iii)(I) The Secretary may reject the selection of the
13 accredited person identified in the notice under subpara-
14 graph (A)(ii) if the Secretary provides to the owner or op-
15 erator of the establishment a statement of the reasons for
16 such rejection. Reasons for the rejection may include that
17 the establishment or the accredited person, as the case
18 may be, has failed to fully respond to the request, or that
19 the Secretary has concerns regarding the relationship be-
20 tween the establishment and such accredited person.

21 “(II) If the Secretary rejects the selection of an ac-
22 credited person by the owner or operator of a device estab-
23 lishment, the owner or operator may make an additional
24 selection of an accredited person by submitting to the Sec-
25 retary a notice that identifies the additional selection.

1 Clauses (i) and (ii) of subparagraph (B), and subclause
2 (I) of this clause, apply to the selection of an accredited
3 person through a notice under the preceding sentence in
4 the same manner and to the same extent as such provi-
5 sions apply to a selection of an accredited person through
6 a notice under subparagraph (A)(ii).

7 “(iv) In the case of a device establishment that is de-
8 nied clearance under clause (i) or (ii) or with respect to
9 which the selection of the accredited person is rejected
10 under clause (iii), the Secretary shall designate a person
11 to review the statement of reasons, or statement summa-
12 rizing such evidence, as the case may be, of the Secretary
13 under such clause if, during the 30-day period beginning
14 on the date on which the owner or operator of the estab-
15 lishment receives such statement, the owner or operator
16 requests the review. The review shall commence not later
17 than 30 days after the owner or operator requests the re-
18 view, unless the Secretary and the owner or operator oth-
19 erwise agree.”;

20 (5) in paragraph (7)—

21 (A) by amending subparagraph (A) to read
22 as follows:

23 “(A) Persons accredited under paragraph
24 (2) to conduct inspections shall record in writ-
25 ing their inspection observations and shall

1 present the observations to the device establish-
2 ment's designated representative and describe
3 each observation. Additionally, such accredited
4 person shall prepare an inspection report in a
5 form and manner designated by the Secretary
6 to conduct inspections, taking into consider-
7 ation the goals of international harmonization
8 of quality systems standards. Any official classi-
9 fication of the inspection shall be determined by
10 the Secretary.”; and

11 (B) by adding at the end the following:

12 “(F) For the purpose of setting risk-based
13 inspectional priorities, the Secretary shall ac-
14 cept voluntary submissions of reports of audits
15 assessing conformance with appropriate quality
16 systems standards set by the International Or-
17 ganization for Standardization (ISO) and iden-
18 tified by the Secretary in public notice. If the
19 owner or operator of an establishment elects to
20 submit audit reports under this subparagraph,
21 the owner or operator shall submit all such
22 audit reports with respect to the establishment
23 during the preceding 2-year periods.”; and

24 (6) in paragraphs (10)(C)(iii), by striking
25 “based” and inserting “base”.

1 **SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY**
2 **REVIEW OF PREMARKET NOTIFICATION.**

3 Section 523(c) (21 U.S.C. 360m(c)) is amended by
4 striking “2007” and inserting “2012”.

5 **SEC. 313. REGISTRATION.**

6 (a) ANNUAL REGISTRATION OF PRODUCERS OF
7 DRUGS AND DEVICES.—Section 510(b) (21 U.S.C.
8 359(b)) is amended—

9 (1) by redesignating the existing text as para-
10 graph (1), and indenting and relocating it appro-
11 priately;

12 (2) in paragraph (1), as so redesignated, by
13 striking “or a device or devices”; and

14 (3) by adding at the end the following new
15 paragraph:

16 “(2) Between October 1 and December 31 of
17 each year every person who owns or operates any es-
18 tablishment in any State engaged in the manufac-
19 ture, preparation, propagation, compounding, or
20 processing of a device or devices shall register with
21 the Secretary his name, places of business, and all
22 such establishments.”.

23 (b) REGISTRATION OF FOREIGN ESTABLISH-
24 MENTS.—Section 510(i)(1) (21 U.S.C. 359(i)(1)) is
25 amended—

1 (1) by redesignating the existing text as sub-
2 paragraph (A), and indenting and relocating it ap-
3 propriately;

4 (2) in subparagraph (A), as so redesignated—

5 (A) by striking “processing of a drug or a
6 device that is imported” and inserting “proc-
7 essing of a drug that is imported”; and

8 (B) by striking “or device” each place it
9 appears; and

10 (3) by adding after such subparagraph (A) the
11 following new subparagraph:

12 “(B) Between October 1 and December 31
13 of each year, any establishment within any for-
14 eign country engaged in the manufacture, prep-
15 aration, propagation, compounding, or proc-
16 essing of a device that is imported or offered
17 for import into the United States shall, through
18 electronic means in accordance with the criteria
19 of the Secretary, register with the Secretary the
20 name and place of business of the establish-
21 ment, the name of the United States agent for
22 the establishment, the name of each importer of
23 such device in the United States that is known
24 to the establishment, and the name of each per-
25 son who imports or offers for import such de-

1 vice to the United States for purposes of impor-
2 tation.”.

3 **SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANU-**
4 **FACTURED PREPARED, PROPAGATED AND**
5 **COMPOUNDED BY REGISTRANTS; STATE-**
6 **MENTS; ACCOMPANYING DISCLOSURES.**

7 Section 510(j)(2) (21 U.S.C. 360(j)(2) is amended,
8 in the matter preceding subparagraph (A), to read as fol-
9 lows:

10 “(2) Each person who registers with the Sec-
11 retary under this section shall report to the Sec-
12 retary (i) with regard to drugs, once during the
13 month of June of each year and once during the
14 month of December of each year, and (ii) with re-
15 gard to devices, once each year between October 1
16 and December 31, the following information:”.

17 **SEC. 315. ELECTRONIC REGISTRATION AND LISTING.**

18 Section 510(p) (21 U.S.C. 360(p)) is amended to
19 read as follows:

20 “(p)(1) With regard to any establishment engaged in
21 the manufacture, preparation, propagation, compounding,
22 or processing of a drug, registrations under subsections
23 (b), (c), (d), and (i) of this section (including the submis-
24 sion of updated information) shall be submitted to the
25 Secretary by electronic means, upon a finding by the Sec-

1 retary that the electronic receipt of such registrations is
 2 feasible, unless the Secretary grants a request for waiver
 3 of such requirement because use of electronic means is not
 4 reasonable for the person requesting such waiver.

5 “(2) With regard to any establishment engaged in the
 6 manufacture, preparation, propagation, compounding, or
 7 processing of a device, the registration and listing infor-
 8 mation required by this section shall be submitted to the
 9 Secretary by electronic means, unless the Secretary grants
 10 a waiver because electronic registration and listing is not
 11 reasonable for the person requesting such waiver.”.

12 **TITLE IV—PEDIATRIC MEDICAL** 13 **PRODUCTS**

14 **Subtitle A—Best Pharmaceuticals** 15 **for Children**

16 **SEC. 401. SHORT TITLE.**

17 This subtitle may be cited as the “Best Pharma-
 18 ceuticals for Children Amendments of 2007”.

19 **SEC. 402. PEDIATRIC STUDIES OF DRUGS.**

20 (a) IN GENERAL.—Section 505A of the Federal
 21 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
 22 amended—

23 (1) in subsection (a), by inserting before the pe-
 24 riod at the end the following: “, and, at the discre-

1 tion of the Secretary, may include preclinical stud-
2 ies”;

3 (2) in subsection (b)—

4 (A) in paragraph (1)(A)(i), by striking
5 “(D)” both places it appears and inserting
6 “(E)”;

7 (B) in paragraph (1)(A)(ii), by striking
8 “(D)” and inserting “(E)”;

9 (C) by striking “(1)(A)(i)” and inserting
10 “(A)(i)(I)”;

11 (D) by striking “(ii) the” and inserting
12 “(II) the”;

13 (E) by striking “(B) if the drug is des-
14 ignated” and inserting “(ii) if the drug is des-
15 ignated”;

16 (F) by striking “(2)(A)” and inserting
17 “(B)(i)”;

18 (G) by striking “(i) a listed patent” and
19 inserting “(I) a listed patent”;

20 (H) by striking “(ii) a listed patent” and
21 inserting “(II) a listed patent”;

22 (I) by striking “(B) if the drug is the sub-
23 ject” and inserting “(ii) if the drug is the sub-
24 ject”;

1 (J) by striking “If” and all that follows
2 through “subsection (d)(3)” and inserting the
3 following:

4 “(1) IN GENERAL.—Except as provided in para-
5 graph (2), if, prior to approval of an application that
6 is submitted under section 505(b)(1), the Secretary
7 determines that information relating to the use of a
8 new drug in the pediatric population may produce
9 health benefits in that population, the Secretary
10 makes a written request for pediatric studies (which
11 shall include a timeframe for completing such stud-
12 ies), the applicant agrees to the request, such stud-
13 ies are completed using appropriate formulations for
14 each age group for which the study is requested
15 within any such timeframe, and the reports thereof
16 are submitted and accepted in accordance with sub-
17 section (d)(3), and if the Secretary determines that
18 labeling changes are appropriate, such changes are
19 made within the timeframe requested by the Sec-
20 retary—”; and

21 (K) by adding at the end the following:

22 “(2) EXCEPTION.—The Secretary shall not ex-
23 tend a period referred to in paragraph (1)(A) or in
24 paragraph (1)(B) if the determination made under

1 subsection (d)(3) is made less than 9 months prior
 2 to the expiration of such period.”;

3 (3) in subsection (c)—

4 (A) in paragraph (1)(A)(i), by striking
 5 “(D)” both places it appears and inserting
 6 “(E)”;

7 (B) in paragraph (1)(A)(ii), by striking
 8 “(D)” and inserting “(E)”;

9 (C) by striking “(1)(A)(i)” and inserting
 10 “(A)(i)(I)”;

11 (D) by striking “(ii) the” and inserting
 12 “(II) the”;

13 (E) by striking “(B) if the drug is des-
 14 ignated” and inserting “(ii) if the drug is des-
 15 ignated”;

16 (F) by striking “(2)(A)” and inserting
 17 “(B)(i)”;

18 (G) by striking “(i) a listed patent” and
 19 inserting “(I) a listed patent”;

20 (H) by striking “(ii) a listed patent” and
 21 inserting “(II) a listed patent”;

22 (I) by striking “(B) if the drug is the sub-
 23 ject” and inserting “(ii) if the drug is the sub-
 24 ject”;

1 (J) by striking “If” and all that follows
2 through “subsection (d)(3)” and inserting the
3 following:

4 “(1) IN GENERAL.—Except as provided in para-
5 graph (2), if the Secretary determines that informa-
6 tion relating to the use of an approved drug in the
7 pediatric population may produce health benefits in
8 that population and makes a written request to the
9 holder of an approved application under section
10 505(b)(1) for pediatric studies (which shall include
11 a timeframe for completing such studies), the holder
12 agrees to the request, such studies are completed
13 using appropriate formulations for each age group
14 for which the study is requested within any such
15 timeframe, and the reports thereof are submitted
16 and accepted in accordance with subsection (d)(3),
17 and if the Secretary determines that labeling
18 changes are appropriate, such changes are made
19 within the timeframe requested by the Secretary—
20 ”; and

21 (K) by adding at the end the following:

22 “(2) EXCEPTION.—The Secretary shall not ex-
23 tend a period referred to in paragraph (1)(A) or in
24 paragraph (1)(B) if the determination made under

1 subsection (d)(3) is made less than 9 months prior
2 to the expiration of such period.”;

3 (4) by striking subsection (d) and inserting the
4 following:

5 “(d) CONDUCT OF PEDIATRIC STUDIES.—

6 “(1) REQUEST FOR STUDIES.—

7 “(A) IN GENERAL.—The Secretary may,
8 after consultation with the sponsor of an appli-
9 cation for an investigational new drug under
10 section 505(i), the sponsor of an application for
11 a new drug under section 505(b)(1), or the
12 holder of an approved application for a drug
13 under section 505(b)(1), issue to the sponsor or
14 holder a written request for the conduct of pedi-
15 atric studies for such drug. In issuing such re-
16 quest, the Secretary shall take into account
17 adequate representation of children of ethnic
18 and racial minorities. Such request to conduct
19 pediatric studies shall be in writing and shall
20 include a timeframe for such studies and a re-
21 quest to the sponsor or holder to propose pedi-
22 atric labeling resulting from such studies.

23 “(B) SINGLE WRITTEN REQUEST.—A sin-
24 gle written request—

1 “(i) may relate to more than 1 use of
2 a drug; and

3 “(ii) may include uses that are both
4 approved and unapproved.

5 “(2) WRITTEN REQUEST FOR PEDIATRIC STUD-
6 IES.—

7 “(A) REQUEST AND RESPONSE.—

8 “(i) IN GENERAL.—If the Secretary
9 makes a written request for pediatric stud-
10 ies (including neonates, as appropriate)
11 under subsection (b) or (c), the applicant
12 or holder, not later than 180 days after re-
13 ceiving the written request, shall respond
14 to the Secretary as to the intention of the
15 applicant or holder to act on the request
16 by—

17 “(I) indicating when the pediatric
18 studies will be initiated, if the appli-
19 cant or holder agrees to the request;
20 or

21 “(II) indicating that the appli-
22 cant or holder does not agree to the
23 request and the reasons for declining
24 the request.

1 “(ii) DISAGREE WITH REQUEST.—If,
2 on or after the date of enactment of the
3 Best Pharmaceuticals for Children Amend-
4 ments of 2007, the applicant or holder
5 does not agree to the request on the
6 grounds that it is not possible to develop
7 the appropriate pediatric formulation, the
8 applicant or holder shall submit to the Sec-
9 retary the reasons such pediatric formula-
10 tion cannot be developed.

11 “(B) ADVERSE EVENT REPORTS.—An ap-
12 plicant or holder that, on or after the date of
13 enactment of the Best Pharmaceuticals for
14 Children Amendments of 2007, agrees to the
15 request for such studies shall provide the Sec-
16 retary, at the same time as submission of the
17 reports of such studies, with all postmarket ad-
18 verse event reports regarding the drug that is
19 the subject of such studies and are available
20 prior to submission of such reports.

21 “(3) MEETING THE STUDIES REQUIREMENT.—
22 Not later than 180 days after the submission of the
23 reports of the studies, the Secretary shall accept or
24 reject such reports and so notify the sponsor or
25 holder. The Secretary’s only responsibility in accept-

1 ing or rejecting the reports shall be to determine,
2 within the 180 days, whether the studies fairly re-
3 spond to the written request, have been conducted in
4 accordance with commonly accepted scientific prin-
5 ciples and protocols, and have been reported in ac-
6 cordance with the requirements of the Secretary for
7 filing.

8 “(4) EFFECT OF SUBSECTION.—Nothing in this
9 subsection alters or amends section 301(j) of this
10 Act or section 552 of title 5 or section 1905 of title
11 18, United States Code.”;

12 (5) by striking subsections (e) and (f) and in-
13 serting the following:

14 “(e) NOTICE OF DETERMINATIONS ON STUDIES RE-
15 QUIREMENT.—

16 “(1) IN GENERAL.—The Secretary shall publish
17 a notice of any determination, made on or after the
18 date of enactment of the Best Pharmaceuticals for
19 Children Amendments of 2007, that the require-
20 ments of subsection (d) have been met and that sub-
21 missions and approvals under subsection (b)(2) or
22 (j) of section 505 for a drug will be subject to the
23 provisions of this section. Such notice shall be pub-
24 lished not later than 30 days after the date of the
25 Secretary’s determination regarding market exclu-

1 sivity and shall include a copy of the written request
2 made under subsection (b) or (c).

3 “(2) IDENTIFICATION OF CERTAIN DRUGS.—

4 The Secretary shall publish a notice identifying any
5 drug for which, on or after the date of enactment of
6 the Best Pharmaceuticals for Children Amendments
7 of 2007, a pediatric formulation was developed,
8 studied, and found to be safe and effective in the pe-
9 diatric population (or specified subpopulation) if the
10 pediatric formulation for such drug is not introduced
11 onto the market within 1 year of the date that the
12 Secretary publishes the notice described in para-
13 graph (1). Such notice identifying such drug shall be
14 published not later than 30 days after the date of
15 the expiration of such 1 year period.

16 “(f) INTERNAL REVIEW OF WRITTEN REQUESTS
17 AND PEDIATRIC STUDIES.—

18 “(1) INTERNAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall
20 create an internal review committee to review
21 all written requests issued and all reports sub-
22 mitted on or after the date of enactment of the
23 Best Pharmaceuticals for Children Amendments
24 of 2007, in accordance with paragraphs (2) and
25 (3).

1 “(B) MEMBERS.—The committee under
2 subparagraph (A) shall include individuals, each
3 of whom is an employee of the Food and Drug
4 Administration, with the following expertise:

5 “(i) Pediatrics.

6 “(ii) Biopharmacology.

7 “(iii) Statistics.

8 “(iv) Drugs and drug formulations.

9 “(v) Legal issues.

10 “(vi) Appropriate expertise, such as
11 expertise in child and adolescent psychi-
12 atry, pertaining to the pediatric product
13 under review.

14 “(vii) One or more experts from the
15 Office of Pediatric Therapeutics, which
16 may include an expert in pediatric ethics.

17 “(viii) Other individuals as designated
18 by the Secretary.

19 “(C) ACTION BY COMMITTEE.—The com-
20 mittee established under this paragraph may
21 perform a function under this section using ap-
22 propriate members of the committee under sub-
23 paragraph (B) and need not convene all mem-
24 bers of the committee under subparagraph (B)

1 in order to perform a function under this sec-
2 tion.

3 “(D) DOCUMENTATION OF COMMITTEE AC-
4 TION.—The committee established under this
5 paragraph shall document for each function
6 under paragraphs (2) and (3), which members
7 of the committee participated in such function.

8 “(2) REVIEW OF WRITTEN REQUESTS.—All
9 written requests under this section shall be reviewed
10 and approved by the committee established under
11 paragraph (1) prior to being issued.

12 “(3) REVIEW OF PEDIATRIC STUDIES.—The
13 committee established under paragraph (1) shall re-
14 view all studies conducted pursuant to this section to
15 make a recommendation to the Secretary whether to
16 accept or reject such reports under subsection
17 (d)(3).

18 “(4) TRACKING PEDIATRIC STUDIES AND LA-
19 BELING CHANGES.—The committee established
20 under paragraph (1) shall be responsible for track-
21 ing and making available to the public, in an easily
22 accessible manner, including through posting on the
23 website of the Food and Drug Administration—

24 “(A) the number of studies conducted
25 under this section;

1 “(B) the specific drugs and drug uses, in-
2 cluding labeled and off-labeled indications, stud-
3 ied under this section;

4 “(C) the types of studies conducted under
5 this section, including trial design, the number
6 of pediatric patients studied, and the number of
7 centers and countries involved;

8 “(D) the number of pediatric formulations
9 developed and the number of pediatric formula-
10 tions not developed and the reasons such for-
11 mulations were not developed;

12 “(E) the labeling changes made as a result
13 of studies conducted under this section;

14 “(F) an annual summary of labeling
15 changes made as a result of studies conducted
16 under this section for distribution pursuant to
17 subsection (k)(2);

18 “(G) information regarding reports sub-
19 mitted on or after the date of enactment of the
20 Best Pharmaceuticals for Children Amendments
21 of 2007; and

22 “(H) the number of times the committee
23 established under paragraph (1) made a rec-
24 ommendation to the Secretary under paragraph
25 (3), the number of times the Secretary did not

1 follow such a recommendation to accept reports
 2 under subsection (d)(3), and the number of
 3 times the Secretary did not follow such a rec-
 4 ommendation to reject such reports under sec-
 5 tion (d)(3).

6 “(5) COMMITTEE.—The committee established
 7 under paragraph (1) is the committee established
 8 under section 505B(f)(1).”;

9 (6) in subsection (g)—

10 (A) in paragraph (1)—

11 (i) by striking “(c)(1)(A)(ii)” and in-
 12 serting “(c)(1)(A)(i)(II)”; and

13 (ii) by striking “(c)(2)” and inserting
 14 “(c)(1)(B)”;

15 (B) in paragraph (2), by striking
 16 “(c)(1)(B)” and inserting “(c)(1)(A)(ii)”;

17 (C) by redesignating paragraphs (1) and
 18 (2) as subparagraphs (A) and (B), respectively;

19 (D) by striking “LIMITATIONS.—A drug”
 20 and inserting “LIMITATIONS.—

21 “(1) IN GENERAL.—Notwithstanding subsection
 22 (c)(2), a drug”; and

23 (E) by adding at the end the following:

24 “(2) EXCLUSIVITY ADJUSTMENT.—

25 “(A) ADJUSTMENT.—

1 “(i) IN GENERAL.—With respect to
2 any drug, if the organization designated
3 under subparagraph (B) notifies the Sec-
4 retary that the combined annual gross
5 sales for all drugs with the same active
6 moiety exceeded \$1,000,000,000 in any
7 calendar year prior to the time the sponsor
8 or holder agrees to the initial written re-
9 quest pursuant to subsection (d)(2), then
10 each period of market exclusivity deemed
11 or extended under subsection (b) or (c)
12 shall be reduced by 3 months for such
13 drug.

14 “(ii) DETERMINATION.—The deter-
15 mination under clause (i) of the combined
16 annual gross sales shall be determined—

17 “(I) taking into account only
18 those sales within the United States;
19 and

20 “(II) taking into account only the
21 sales of all drugs with the same active
22 moiety of the sponsor or holder and
23 its affiliates.

24 “(B) DESIGNATION.—The Secretary shall
25 designate an organization other than the Food

1 and Drug Administration to evaluate whether
 2 the combined annual gross sales for all drugs
 3 with the same active moiety exceeded
 4 \$1,000,000,000 in a calendar year as described
 5 in subparagraph (A). Prior to designating such
 6 organization, the Secretary shall determine that
 7 such organization is independent and is quali-
 8 fied to evaluate the sales of pharmaceutical
 9 products. The Secretary shall re-evaluate the
 10 designation of such organization once every 3
 11 years.

12 “(C) NOTIFICATION.—Once a year at a
 13 time designated by the Secretary, the organiza-
 14 tion designated under subparagraph (B) shall
 15 notify the Food and Drug Administration of all
 16 drugs with the same active moiety with com-
 17 bined annual gross sales that exceed
 18 \$1,000,000,000 during the previous calendar
 19 year.”;

20 (7) in subsection (i)—

21 (A) in the heading, by striking “SUPPLE-
 22 MENTS” and inserting “CHANGES”;

23 (B) in paragraph (1)—

24 (i) in the heading, by inserting “AP-
 25 PPLICATIONS AND” after “PEDIATRIC”;

1 (ii) by inserting “application or” after
2 “Any”;

3 (iii) by striking “change pursuant to a
4 report on a pediatric study under” and in-
5 serting “change as a result of any pedi-
6 atric study conducted pursuant to”; and

7 (iv) by inserting “application or” after
8 “to be a priority”; and

9 (C) in paragraph (2)(A), by—

10 (i) striking “If the Commissioner”
11 and inserting “If, on or after the date of
12 enactment of the Best Pharmaceuticals for
13 Children Amendments of 2007, the Com-
14 missioner”; and

15 (ii) striking “an application with” and
16 all that follows through “on appropriate”
17 and inserting “the sponsor and the Com-
18 missioner have been unable to reach agree-
19 ment on appropriate”;

20 (8) by striking subsection (m);

21 (9) by redesignating subsections (j), (k), (l),
22 and (n), as subsections (k), (m), (o), and (p), respec-
23 tively;

24 (10) by inserting after subsection (i) the fol-
25 lowing:

1 “(j) OTHER LABELING CHANGES.—If, on or after the
 2 date of enactment of the Best Pharmaceuticals for Chil-
 3 dren Amendments of 2007, the Secretary determines that
 4 a pediatric study conducted under this section does or does
 5 not demonstrate that the drug that is the subject of the
 6 study is safe and effective, including whether such study
 7 results are inconclusive, in pediatric populations or sub-
 8 populations, the Secretary shall order the labeling of such
 9 product to include information about the results of the
 10 study and a statement of the Secretary’s determination.”;

11 (11) in subsection (k), as redesignated by para-
 12 graph (9)—

13 (A) in paragraph (1)—

14 (i) by striking “a summary of the
 15 medical and” and inserting “the medical,
 16 statistical, and”; and

17 (ii) by striking “for the supplement”
 18 and all that follows through the period and
 19 inserting “under subsection (b) or (c).”;

20 (B) by redesignating paragraph (2) as
 21 paragraph (3); and

22 (C) by inserting after paragraph (1) the
 23 following:

24 “(2) DISSEMINATION OF INFORMATION RE-
 25 GARDING LABELING CHANGES.—Beginning on the

1 date of enactment of the Best Pharmaceuticals for
2 Children Amendments of 2007, the Secretary shall
3 require that the sponsors of the studies that result
4 in labeling changes that are reflected in the annual
5 summary developed pursuant to subsection (f)(4)(F)
6 distribute, at least annually (or more frequently if
7 the Secretary determines that it would be beneficial
8 to the public health), such information to physicians
9 and other health care providers.”;

10 (12) by inserting after subsection (k), as reded-
11 icated by paragraph (9), the following:

12 “(l) ADVERSE EVENT REPORTING.—

13 “(1) REPORTING IN YEAR ONE.—Beginning on
14 the date of enactment of the Best Pharmaceuticals
15 for Children Amendments of 2007, during the 1-year
16 period beginning on the date a labeling change is
17 made pursuant to subsection (i), the Secretary shall
18 ensure that all adverse event reports that have been
19 received for such drug (regardless of when such re-
20 port was received) are referred to the Office of Pedi-
21 atric Therapeutics established under section 6 of the
22 Best Pharmaceuticals for Children Act (Public Law
23 107–109). In considering such reports, the Director
24 of such Office shall provide for the review of the re-
25 port by the Pediatric Advisory Committee, including

1 obtaining any recommendations of such Committee
2 regarding whether the Secretary should take action
3 under this section in response to such reports.

4 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
5 lowing the 1-year period described in paragraph (1),
6 the Secretary shall, as appropriate, refer to the Of-
7 fice of Pediatric Therapeutics all pediatric adverse
8 event reports for a drug for which a pediatric study
9 was conducted under this section. In considering
10 such reports, the Director of such Office may pro-
11 vide for the review of such reports by the Pediatric
12 Advisory Committee, including obtaining any rec-
13 ommendation of such Committee regarding whether
14 the Secretary should take action in response to such
15 reports.

16 “(3) EFFECT.—The requirements of this sub-
17 section shall supplement, not supplant, other review
18 of such adverse event reports by the Secretary.”;

19 (13) by inserting after subsection (m), as reded-
20 icated by paragraph (9), the following:

21 “(n) REFERRAL IF PEDIATRIC STUDIES NOT COM-
22 PLETED.—

23 “(1) IN GENERAL.—Beginning on the date of
24 enactment of the Best Pharmaceuticals for Children
25 Amendments of 2007, if pediatric studies of a drug

1 have not been completed under subsection (d) and if
2 the Secretary, through the committee established
3 under subsection (f), determines that there is a con-
4 tinuing need for information relating to the use of
5 the drug in the pediatric population (including neo-
6 nates, as appropriate), the Secretary shall carry out
7 the following:

8 “(A) For a drug for which a listed patent
9 has not expired, make a determination regard-
10 ing whether an assessment shall be required to
11 be submitted under section 505B. Prior to mak-
12 ing such determination, the Secretary may take
13 not more than 60 days to certify whether the
14 Foundation for the National Institutes of
15 Health has sufficient funding at the time of
16 such certification to initiate 1 or more of the
17 pediatric studies of such drug referred to in the
18 sentence preceding this paragraph and fund 1
19 or more of such studies in their entirety. Only
20 if the Secretary makes such certification in the
21 affirmative, the Secretary shall refer such pedi-
22 atric study or studies to the Foundation for the
23 National Institutes of Health for the conduct of
24 such study or studies.

1 “(B) For a drug that has no listed patents
2 or has 1 or more listed patents that have ex-
3 pired, the Secretary shall refer the drug for in-
4 clusion on the list established under section
5 409I of the Public Health Service Act for the
6 conduct of studies.

7 “(2) PUBLIC NOTICE.—The Secretary shall give
8 the public notice of—

9 “(A) a decision under paragraph (1)(A)
10 not to require an assessment under section
11 505B and the basis for such decision; and

12 “(B) any referral under paragraph (1)(B)
13 of a drug for inclusion on the list established
14 under section 409I of the Public Health Service
15 Act.

16 “(3) EFFECT OF SUBSECTION.—Nothing in this
17 subsection alters or amends section 301(j) of this
18 Act or section 552 of title 5 or section 1905 of title
19 18, United States Code.”; and

20 (14) in subsection (p), as redesignated by para-
21 graph (9)—

22 (A) striking “6-month period” and insert-
23 ing “3-month or 6-month period”;

24 (B) by striking “subsection (a)” and in-
25 serting “subsection (b)”; and

1 (C) by striking “2007” both places it ap-
2 pears and inserting “2012”.

3 (b) EFFECTIVE DATE.—Except as otherwise provided
4 in the amendments made by subsection (a), such amend-
5 ments shall apply to written requests under section 505A
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355a) made after the date of enactment of this subtitle.

8 **SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

9 Section 409I of the Public Health Service Act (42
10 U.S.C. 284m) is amended—

11 (1) by striking subsections (a) and (b) and in-
12 serting the following:

13 “(a) LIST OF PRIORITY ISSUES IN PEDIATRIC
14 THERAPEUTICS.—

15 “(1) IN GENERAL.—Not later than 1 year after
16 the date of enactment of the Best Pharmaceuticals
17 for Children Amendments of 2007, the Secretary,
18 acting through the Director of the National Insti-
19 tutes of Health and in consultation with the Com-
20 missioner of Food and Drugs and experts in pedi-
21 atric research, shall develop and publish a priority
22 list of needs in pediatric therapeutics, including
23 drugs or indications that require study. The list
24 shall be revised every 3 years.

1 “(2) CONSIDERATION OF AVAILABLE INFORMA-
2 TION.—In developing and prioritizing the list under
3 paragraph (1), the Secretary shall consider—

4 “(A) therapeutic gaps in pediatrics that
5 may include developmental pharmacology,
6 pharmacogenetic determinants of drug re-
7 sponse, metabolism of drugs and biologics in
8 children, and pediatric clinical trials;

9 “(B) particular pediatric diseases, dis-
10 orders or conditions where more complete
11 knowledge and testing of therapeutics, including
12 drugs and biologics, may be beneficial in pedi-
13 atric populations; and

14 “(C) the adequacy of necessary infrastruc-
15 ture to conduct pediatric pharmacological re-
16 search, including research networks and trained
17 pediatric investigators.

18 “(b) PEDIATRIC STUDIES AND RESEARCH.—The
19 Secretary, acting through the National Institutes of
20 Health, shall award funds to entities that have the exper-
21 tise to conduct pediatric clinical trials or other research
22 (including qualified universities, hospitals, laboratories,
23 contract research organizations, practice groups, federally
24 funded programs such as pediatric pharmacology research
25 units, other public or private institutions, or individuals)

1 to enable the entities to conduct the drug studies or other
2 research on the issues described in subsection (a). The
3 Secretary may use contracts, grants, or other appropriate
4 funding mechanisms to award funds under this sub-
5 section.”;

6 (2) in subsection (c)—

7 (A) in the heading, by striking “CON-
8 TRACTS” and inserting “PROPOSED PEDIATRIC
9 STUDY REQUESTS”;

10 (B) by striking paragraphs (4) and (12);

11 (C) by redesignating paragraphs (1), (2),
12 and (3), as paragraphs (2), (3), and (4);

13 (D) by inserting before paragraph (2), as
14 redesignated by subparagraph (C), the fol-
15 lowing:

16 “(1) SUBMISSION OF PROPOSED PEDIATRIC
17 STUDY REQUEST.—The Director of the National In-
18 stitutes of Health shall, as appropriate, submit pro-
19 posed pediatric study requests for consideration by
20 the Commissioner of Food and Drugs for pediatric
21 studies of a specific pediatric indication identified
22 under subsection (a). Such a proposed pediatric
23 study request shall be made in a manner equivalent
24 to a written request made under subsection (b) or
25 (c) of section 505A of the Federal Food, Drug, and

1 Cosmetic Act, including with respect to the informa-
2 tion provided on the pediatric studies to be con-
3 ducted pursuant to the request. The Director of the
4 National Institutes of Health may submit a pro-
5 posed pediatric study request for a drug for which—

6 “(A)(i) there is an approved application
7 under section 505(j) of the Federal Food,
8 Drug, and Cosmetic Act; or

9 “(ii) there is a submitted application that
10 could be approved under the criteria of section
11 505(j) of the Federal Food, Drug, and Cos-
12 metic Act;

13 “(B) there is no patent protection or mar-
14 ket exclusivity protection for at least 1 form of
15 the drug under the Federal Food, Drug, and
16 Cosmetic Act; and

17 “(C) additional studies are needed to as-
18 sess the safety and effectiveness of the use of
19 the drug in the pediatric population.”;

20 (E) in paragraph (2), as redesignated by
21 subparagraph (C)—

22 (i) by inserting “based on the pro-
23 posed pediatric study request for the indi-
24 cation or indications submitted pursuant to

1 paragraph (1)” after “issue a written re-
2 quest”;

3 (ii) by striking “in the list described
4 in subsection (a)(1)(A) (except clause
5 (iv))” and inserting “under subsection
6 (a)”;

7 (iii) by inserting “and using appro-
8 priate formulations for each age group for
9 which the study is requested” before the
10 period at the end;

11 (F) in paragraph (3), as redesignated by
12 subparagraph (C)—

13 (i) in the heading, by striking “CON-
14 TRACT”;

15 (ii) by striking “paragraph (1)” and
16 inserting “paragraph (2)”;

17 (iii) by striking “or if a referral de-
18 scribed in subsection (a)(1)(A)(iv) is
19 made,”;

20 (iv) by striking “for contract pro-
21 posals” and inserting “for proposals”; and

22 (v) by inserting “in accordance with
23 subsection (b)” before the period at the
24 end;

(G) in paragraph (4), as redesignated by subparagraph (C)—

(i) by striking “contract”; and

(ii) by striking “paragraph (2)” and inserting “paragraph (3)”;

(H) in paragraph (5)—

(i) by striking the heading and inserting “CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS”; and

(ii) by striking “A contract” and all that follows through “is submitted” and inserting “A contract, grant, or other funding may be awarded under this section only if a proposal is submitted”;

(I) in paragraph (6)(A)—

(i) by striking “a contract awarded” and inserting “an award”; and

(ii) by inserting “, including a written request if issued” after “with the study”; and

(3) by inserting after subsection (c) the following:

“(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of

1 2007, the Secretary, acting through the Director of the
2 National Institutes of Health, shall study the feasibility
3 of establishing a compilation of information on pediatric
4 drug use and report the findings to Congress.”

5 “(e) AUTHORIZATION OF APPROPRIATIONS.—

6 “(1) IN GENERAL.—There are authorized to be
7 appropriated to carry out this section—

8 “(A) \$200,000,000 for fiscal year 2008;
9 and

10 “(B) such sums as are necessary for each
11 of the 4 succeeding fiscal years.

12 “(2) AVAILABILITY.—Any amount appropriated
13 under paragraph (1) shall remain available to carry
14 out this section until expended.”.

15 **SEC. 404. REPORTS AND STUDIES.**

16 (a) GAO REPORT.—Not later than January 31,
17 2011, the Comptroller General of the United States, in
18 consultation with the Secretary of Health and Human
19 Services, shall submit to Congress a report that addresses
20 the effectiveness of section 505A of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring
22 that medicines used by children are tested and properly
23 labeled, including—

24 (1) the number and importance of drugs for
25 children that are being tested as a result of the

1 amendments made by this subtitle and the impor-
2 tance for children, health care providers, parents,
3 and others of labeling changes made as a result of
4 such testing;

5 (2) the number and importance of drugs for
6 children that are not being tested for their use not-
7 withstanding the provisions of this subtitle and the
8 amendments made by this subtitle, and possible rea-
9 sons for the lack of testing, including whether the
10 number of written requests declined by sponsors or
11 holders of drugs subject to section 505A(g)(2) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355a(g)(2)), has increased or decreased as a result
14 of the amendments made by this subtitle;

15 (3) the number of drugs for which testing is
16 being done and labeling changes required, including
17 the date labeling changes are made and which label-
18 ing changes required the use of the dispute resolu-
19 tion process established pursuant to the amendments
20 made by this subtitle, together with a description of
21 the outcomes of such process, including a description
22 of the disputes and the recommendations of the Pe-
23 diatric Advisory Committee;

24 (4) any recommendations for modifications to
25 the programs established under section 505A of the

1 Federal Food, Drug and Cosmetic Act (21 U.S.C.
2 355a) and section 409I of the Public Health Service
3 Act (42 U.S.C. 284m) that the Secretary determines
4 to be appropriate, including a detailed rationale for
5 each recommendation; and

6 (5)(A) the efforts made by the Secretary to in-
7 crease the number of studies conducted in the
8 neonate population; and

9 (B) the results of those efforts, including efforts
10 made to encourage the conduct of appropriate stud-
11 ies in neonates by companies with products that
12 have sufficient safety and other information to make
13 the conduct of the studies ethical and safe.

14 (b) IOM STUDY.—Not later than 3 years after the
15 date of enactment of this subtitle, the Secretary of Health
16 and Human Services shall enter into a contract with the
17 Institute of Medicine to conduct a study and report to
18 Congress regarding the written requests made and the
19 studies conducted pursuant to section 505A of the Federal
20 Food, Drug, and Cosmetic Act. The Institute of Medicine
21 may devise an appropriate mechanism to review a rep-
22 resentative sample of requests made and studies conducted
23 pursuant to such section in order to conduct such study.
24 Such study shall—

1 (1) review such representative written requests
2 issued by the Secretary since 1997 under sub-
3 sections (b) and (c) of such section 505A;

4 (2) review and assess such representative pedi-
5 atric studies conducted under such subsections (b)
6 and (c) since 1997 and labeling changes made as a
7 result of such studies; and

8 (3) review the use of extrapolation for pediatric
9 subpopulations, the use of alternative endpoints for
10 pediatric populations, neonatal assessment tools, and
11 ethical issues in pediatric clinical trials.

12 **SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.**

13 (a) INVESTMENT IN TOMORROW'S PEDIATRIC RE-
14 SEARCHERS.—Section 452G(2) of the Public Health Serv-
15 ice Act (42 U.S.C. 285g–10(2)) is amended by adding be-
16 fore the period at the end the following: “, including pedi-
17 atric pharmacological research”.

18 (b) PEDIATRIC RESEARCH LOAN REPAYMENT PRO-
19 GRAM.—Section 487F(a)(1) of the Public Health Service
20 Act (42 U.S.C. 288–6(a)(1)) is amended by inserting “in-
21 cluding pediatric pharmacological research,” after “pedi-
22 atric research,”.

1 **SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF**
 2 **HEALTH.**

3 Section 499(c)(1)(C) of the Public Health Service Act
 4 (42 U.S.C. 290b(c)(1)(C)) is amended by striking “and
 5 studies listed by the Secretary pursuant to section
 6 409I(a)(1)(A) of the is Act and referred under section
 7 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic
 8 Act (21 U.S.C. 355(a)(d)(4)(C))” and inserting “and stud-
 9 ies for which the Secretary issues a certification under sec-
 10 tion 505A(n)(1)(A) of the Federal Food, Drug, and Cos-
 11 metic Act (21 U.S.C. 355a(n)(1)(A))”.

12 **SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.**

13 Section 14 of the Best Pharmaceuticals for Children
 14 Act (42 U.S.C. 284m note) is amended by adding at the
 15 end the following:

16 “(d) CONTINUATION OF OPERATION OF COM-
 17 MITTEE.—Notwithstanding section 14 of the Federal Ad-
 18 visory Committee Act (5 U.S.C. App.), the advisory com-
 19 mittee shall continue to operate during the 5-year period
 20 beginning on the date of enactment of the Best Pharma-
 21 ceuticals for Children Amendments of 2007.”.

22 **SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**
 23 **DRUGS ADVISORY COMMITTEE.**

24 Section 15 of the Best Pharmaceuticals for Children
 25 Act (42 U.S.C. 284m note) is amended—

26 (1) in subsection (a)—

1 (A) in paragraph (1)—

2 (i) in subparagraph (B), by striking
3 “and” after the semicolon;

4 (ii) in subparagraph (C), by striking
5 the period at the end and inserting “;
6 and”; and

7 (iii) by adding at the end the fol-
8 lowing:

9 “(D) provide recommendations to the in-
10 ternal review committee created under section
11 505A(f) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 355a(f)) regarding the
13 implementation of amendments to sections
14 505A and 505B of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 355a and 355c)
16 with respect to the treatment of pediatric can-
17 cers.”; and

18 (B) by adding at the end the following:

19 “(3) CONTINUATION OF OPERATION OF SUB-
20 COMMITTEE.—Notwithstanding section 14 of the
21 Federal Advisory Committee Act (5 U.S.C. App.),
22 the Subcommittee shall continue to operate during
23 the 5-year period beginning on the date of enact-
24 ment of the Best Pharmaceuticals for Children
25 Amendments of 2007.”; and

1 (2) in subsection (d), by striking “2003” and
2 inserting “2009”.

3 **SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RE-**
4 **LATING TO TOLL-FREE NUMBER FOR AD-**
5 **VERSE EVENTS ON LABELING FOR HUMAN**
6 **DRUG PRODUCTS.**

7 (a) IN GENERAL.—Notwithstanding subchapter II of
8 chapter 5, and chapter 7, of title 5, United States Code
9 (commonly known as the “Administrative Procedure Act”) and
10 any other provision of law, the proposed rule issued
11 by the Commissioner of Food and Drugs entitled “Toll-
12 Free Number for Reporting Adverse Events on Labeling
13 for Human Drug Products”, 69 Fed. Reg. 21778, (April
14 22, 2004) shall take effect on January 1, 2008, unless
15 such Commissioner issues the final rule before such date.

16 (b) LIMITATION.—The proposed rule that takes ef-
17 fect under subsection (a), or the final rule described under
18 subsection (a), shall, notwithstanding section 17(a) of the
19 Best Pharmaceuticals for Children Act (21 U.S.C.
20 355b(a)), not apply to a drug—

21 (1) for which an application is approved under
22 section 505 of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355);

24 (2) that is not described under section
25 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

Subtitle B—Pediatric Research Improvement

SEC. 411. SHORT TITLE.

This subtitle may be cited as the “Pediatric Research Improvement Act”.

SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS, AND DEFERRALS.

Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(1) in paragraph (4)(C), by adding at the end the following: “An applicant seeking either a partial or full waiver on this ground shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant’s submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration”;

(2) in paragraph (2)(B), by adding at the end the following:

1 “(iii) INFORMATION ON EXTRAPO-
 2 LATION.—A brief documentation of the sci-
 3 entific data supporting the conclusion
 4 under clauses (i) and (ii) shall be included
 5 in any pertinent reviews for the application
 6 under section 505 or section 351 of the
 7 Public Health Service Act.”; and

8 (3) by striking paragraph (3) and inserting the
 9 following:

10 “(3) DEFERRAL.—

11 “(A) IN GENERAL.—On the initiative of
 12 the Secretary or at the request of the applicant,
 13 the Secretary may defer submission of some or
 14 all assessments required under paragraph (1)
 15 until a specified date after approval of the drug
 16 or issuance of the license for a biological prod-
 17 uct if—

18 “(i) the Secretary finds that—

19 “(I) the drug or biological prod-
 20 uct is ready for approval for use in
 21 adults before pediatric studies are
 22 complete;

23 “(II) pediatric studies should be
 24 delayed until additional safety or ef-

1 fectiveness data have been collected;

2 or

3 “(III) there is another appro-

4 priate reason for deferral; and

5 “(ii) the applicant submits to the Sec-

6 retary—

7 “(I) certification of the grounds

8 for deferring the assessments;

9 “(II) a description of the planned

10 or ongoing studies;

11 “(III) evidence that the studies

12 are being conducted or will be con-

13 ducted with due diligence and at the

14 earliest possible time; and

15 “(IV) a timeline for the comple-

16 tion of such studies.

17 “(B) ANNUAL REVIEW.—

18 “(i) IN GENERAL.—On an annual

19 basis following the approval of a deferral

20 under subparagraph (A), the applicant

21 shall submit to the Secretary the following

22 information:

23 “(I) Information detailing the

24 progress made in conducting pediatric

25 studies.

1 “(II) If no progress has been
2 made in conducting such studies, evi-
3 dence and documentation that such
4 studies will be conducted with due
5 diligence and at the earliest possible
6 time.

7 “(ii) PUBLIC AVAILABILITY.—The in-
8 formation submitted through the annual
9 review under clause (i) shall promptly be
10 made available to the public in an easily
11 accessible manner, including through the
12 website of the Food and Drug Administra-
13 tion.”.

14 **SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA**
15 **FOR ALREADY MARKETED PRODUCTS.**

16 Section 505B(b) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355c(b)) is amended—

18 (1) by striking paragraph (1) and inserting the
19 following:

20 “(1) IN GENERAL.—After providing notice in
21 the form of a written request under section 505A
22 that was declined by the sponsor or holder, or a let-
23 ter referencing such declined written request, and an
24 opportunity for written response and a meeting,
25 which may include an advisory committee meeting,

1 the Secretary may (by order in the form of a letter)
2 require the sponsor or holder of an approved appli-
3 cation for a drug under section 505 or the holder of
4 a license for a biological product under section 351
5 of the Public Health Service Act (42 U.S.C. 262) to
6 submit by a specified date the assessments described
7 in subsection (a)(2) and the written request, as ap-
8 propriate, for the labeled indication or indications, if
9 the Secretary finds that—

10 “(A)(i) the drug or biological product is
11 used for a substantial number of pediatric pa-
12 tients for the labeled indications; and

13 “(ii) adequate pediatric labeling could con-
14 fer a benefit on pediatric patients;

15 “(B) there is reason to believe that the
16 drug or biological product would represent a
17 meaningful therapeutic benefit over existing
18 therapies for pediatric patients for 1 or more of
19 the claimed indications; or

20 “(C) the absence of adequate pediatric la-
21 beling could pose a risk to pediatric patients.”;

22 (2) in paragraph (2)(C), by adding at the end
23 the following: “An applicant seeking either a partial
24 or full waiver shall submit to the Secretary docu-
25 mentation detailing why a pediatric formulation can-

not be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration.”; and

(3) by striking paragraph (3) and inserting the following:

“(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.”.

**SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS;
ADVERSE EVENT REPORTING; LABELING
CHANGES; AND PEDIATRIC ASSESSMENTS.**

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) redesignating subsection (h) as subsection (j);

(2) in subsection (j), as so redesignated, by striking “505A(n)” and inserting “505A(p)”;

(3) by redesignating subsection (f) as subsection (k);

(4) by redesignating subsection (g) as subsection (l); and

1 (5) by inserting after subsection (e) the fol-
2 lowing:

3 “(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS,
4 PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

5 “(1) REVIEW.—The Secretary shall create an
6 internal committee to review all pediatric assessment
7 requests issued under this section, all pediatric as-
8 sessments conducted under this section, and all de-
9 ferral and waiver requests made pursuant to this
10 section. Such internal committee shall include indi-
11 viduals, each of whom is an employee of the Food
12 and Drug Administration, with the following exper-
13 tise:

14 “(A) Pediatrics.

15 “(B) Biopharmacology.

16 “(C) Statistics.

17 “(D) Drugs and drug formulations.

18 “(E) Pediatric ethics.

19 “(F) Legal issues.

20 “(G) Appropriate expertise, such as exper-
21 tise in child and adolescent psychiatry, per-
22 taining to the pediatric product under review.

23 “(H) 1 or more experts from the Office of
24 Pediatric Therapeutics.

1 “(I) Other individuals as designated by the
2 Secretary.

3 “(2) ACTION BY THE COMMITTEE.—The com-
4 mittee established under paragraph (1) may perform
5 a function under this section using appropriate
6 members of the committee under paragraph (1) and
7 need not convene all members of the committee
8 under paragraph (1) in order to perform a function
9 under this section.

10 “(3) DOCUMENTATION OF COMMITTEE AC-
11 TION.—For each drug or biological product, the
12 committee established under this paragraph shall
13 document for each function under paragraph (4) or
14 (5), which members of the committee participated in
15 such function.

16 “(4) REVIEW OF REQUESTS FOR PEDIATRIC AS-
17 SESSMENTS, DEFERRALS, AND WAIVERS.—All writ-
18 ten requests for a pediatric assessment issued pursu-
19 ant to this section and all requests for deferrals and
20 waivers from the requirement to conduct a pediatric
21 assessment under this section shall be reviewed and
22 approved by the committee established under para-
23 graph (1).

24 “(5) REVIEW OF ASSESSMENTS.—The com-
25 mittee established under paragraph (1) shall review

1 all assessments conducted under this section to de-
2 termine whether such assessments meet the require-
3 ments of this section.

4 “(6) TRACKING OF ASSESSMENTS AND LABEL-
5 ING CHANGES.—The committee established under
6 paragraph (1) is responsible for tracking and mak-
7 ing public in an easily accessible manner, including
8 through posting on the website of the Food and
9 Drug Administration—

10 “(A) the number of assessments conducted
11 under this section;

12 “(B) the specific drugs and drug uses as-
13 sessed under this section;

14 “(C) the types of assessments conducted
15 under this section, including trial design, the
16 number of pediatric patients studied, and the
17 number of centers and countries involved;

18 “(D) the total number of deferrals re-
19 quested and granted under this section, and, if
20 granted, the reasons for such deferrals, the
21 timeline for completion, and the number com-
22 pleted and pending by the specified date, as
23 outlined in subsection (a)(3);

1 “(E) the number of waivers requested and
2 granted under this section, and, if granted, the
3 reasons for the waivers;

4 “(F) the number of pediatric formulations
5 developed and the number of pediatric formula-
6 tions not developed and the reasons any such
7 formulations were not developed;

8 “(G) the labeling changes made as a result
9 of assessments conducted under this section;

10 “(H) an annual summary of labeling
11 changes made as a result of assessments con-
12 ducted under this section for distribution pursu-
13 ant to subsection (i)(2); and

14 “(I) an annual summary of the informa-
15 tion submitted pursuant to subsection
16 (a)(3)(B).

17 “(7) COMMITTEE.—The committee established
18 under paragraph (1) is the committee established
19 under section 505A(f)(1).

20 “(g) LABELING CHANGES.—

21 “(1) PRIORITY STATUS FOR PEDIATRIC SUP-
22 PLEMENT.—Any supplement to an application under
23 section 505 and section 351 of the Public Health
24 Service Act proposing a labeling change as a result

1 of any pediatric assessments conducted pursuant to
2 this section—

3 “(A) shall be considered a priority supple-
4 ment; and

5 “(B) shall be subject to the performance
6 goals established by the Commissioner for pri-
7 ority drugs.

8 “(2) DISPUTE RESOLUTION.—

9 “(A) REQUEST FOR LABELING CHANGE
10 AND FAILURE TO AGREE.—If the Commissioner
11 determines that a sponsor and the Commis-
12 sioner have been unable to reach agreement on
13 appropriate changes to the labeling for the drug
14 that is the subject of the application or supple-
15 ment, not later than 180 days after the date of
16 the submission of the application or supple-
17 ment—

18 “(i) the Commissioner shall request
19 that the sponsor make any labeling change
20 that the Commissioner determines to be
21 appropriate; and

22 “(ii) if the sponsor does not agree to
23 make a labeling change requested by the
24 Commissioner, the Commissioner shall

1 refer the matter to the Pediatric Advisory
2 Committee.

3 “(B) ACTION BY THE PEDIATRIC ADVISORY
4 COMMITTEE.—Not later than 90 days after re-
5 ceiving a referral under subparagraph (A)(ii),
6 the Pediatric Advisory Committee shall—

7 “(i) review the pediatric study reports;
8 and

9 “(ii) make a recommendation to the
10 Commissioner concerning appropriate la-
11 beling changes, if any.

12 “(C) CONSIDERATION OF RECOMMENDA-
13 TIONS.—The Commissioner shall consider the
14 recommendations of the Pediatric Advisory
15 Committee and, if appropriate, not later than
16 30 days after receiving the recommendation,
17 make a request to the sponsor of the applica-
18 tion or supplement to make any labeling
19 changes that the Commissioner determines to
20 be appropriate.

21 “(D) MISBRANDING.—If the sponsor, with-
22 in 30 days after receiving a request under sub-
23 paragraph (C), does not agree to make a label-
24 ing change requested by the Commissioner, the
25 Commissioner may deem the drug that is the

1 subject of the application or supplement to be
2 misbranded.

3 “(E) NO EFFECT ON AUTHORITY.—Noth-
4 ing in this subsection limits the authority of the
5 United States to bring an enforcement action
6 under this Act when a drug lacks appropriate
7 pediatric labeling. Neither course of action (the
8 Pediatric Advisory Committee process or an en-
9 forcement action referred to in the preceding
10 sentence) shall preclude, delay, or serve as the
11 basis to stay the other course of action.

12 “(3) OTHER LABELING CHANGES.—If the Sec-
13 retary makes a determination that a pediatric as-
14 sessment conducted under this section does or does
15 not demonstrate that the drug that is the subject of
16 such assessment is safe and effective, including
17 whether such assessment results are inconclusive, in
18 pediatric populations or subpopulations, the Sec-
19 retary shall order the labeling of such product to in-
20 clude information about the results of the assess-
21 ment and a statement of the Secretary’s determina-
22 tion.

23 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
24 TION.—

1 “(1) IN GENERAL.—Not later than 180 days
2 after the date of submission of a pediatric assess-
3 ment under this section, the Secretary shall make
4 available to the public in an easily accessible manner
5 the medical, statistical, and clinical pharmacology re-
6 views of such pediatric assessments and shall post
7 such assessments on the website of the Food and
8 Drug Administration.

9 “(2) DISSEMINATION OF INFORMATION RE-
10 GARDING LABELING CHANGES.—The Secretary shall
11 require that the sponsors of the assessments that re-
12 sult in labeling changes that are reflected in the an-
13 nual summary developed pursuant to subsection
14 (f)(4)(H) distribute such information to physicians
15 and other health care providers.

16 “(3) EFFECT OF SUBSECTION.—Nothing in this
17 subsection shall alter or amend section 301(j) of this
18 Act or section 552 of title 5, United States Code, or
19 section 1905 of title 18, United States Code.

20 “(i) ADVERSE EVENT REPORTING.—

21 “(1) REPORTING IN YEAR 1.—During the 1-
22 year period beginning on the date a labeling change
23 is made pursuant to subsection (g), the Secretary
24 shall ensure that all adverse event reports that have
25 been received for such drug (regardless of when such

1 report was received) are referred to the Office of Pe-
2 diatric Therapeutics. In considering such reports,
3 the Director of such Office shall provide for the re-
4 view of the report by the Pediatric Advisory Com-
5 mittee, including obtaining any recommendations of
6 such committee regarding whether the Secretary
7 should take action under this Act in response to
8 such report.

9 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
10 lowing the 1-year period described in paragraph (1),
11 the Secretary shall, as appropriate, refer to the Of-
12 fice of Pediatric Therapeutics with all pediatric ad-
13 verse event reports for a drug for which a pediatric
14 study was conducted under this section. In consid-
15 ering such reports, the Director of such Office may
16 provide for the review of such reports by the Pedi-
17 atric Advisory Committee, including obtaining any
18 recommendation of such Committee regarding
19 whether the Secretary should take action in response
20 to such report.

21 “(3) EFFECT.—The requirements of this sub-
22 section shall supplement, not supplant, other review
23 of such adverse event reports by the Secretary.”.

1 **SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.**

2 Section 505B(c) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 355c) is amended—

4 (1) by striking “estimates” and inserting “de-
5 termines”; and

6 (2) by striking “would” and inserting “could”.

7 **SEC. 416. REPORTS.**

8 (a) INSTITUTE OF MEDICINE STUDY.—

9 (1) IN GENERAL.—Not later than 3 years after
10 the date of enactment of this subtitle, the Secretary
11 shall contract with the Institute of Medicine to con-
12 duct a study and report to Congress regarding the
13 pediatric studies conducted pursuant to section
14 505B of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 355c) since 1997.

16 (2) CONTENT OF STUDY.—The study under
17 paragraph (1) shall review and assess—

18 (A) pediatric studies conducted pursuant
19 to section 505B of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355c) since 1997 and
21 labeling changes made as a result of such stud-
22 ies; and

23 (B) the use of extrapolation for pediatric
24 subpopulations, the use of alternative endpoints
25 for pediatric populations, neonatal assessment
26 tools, number and type of pediatric adverse

1 events, and ethical issues in pediatric clinical
2 trials.

3 (3) REPRESENTATIVE SAMPLE.—The Institute
4 of Medicine may devise an appropriate mechanism to
5 review a representative sample of studies conducted
6 pursuant to section 505B of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355c) from each
8 review division within the Center for Drug Evalua-
9 tion and Research and the Center for Biologics
10 Evaluation and Research in order to make the re-
11 quired assessment.

12 (b) GAO REPORT.—Not later than September 1,
13 2010, the Comptroller General of the United States, in
14 consultation with the Secretary of Health and Human
15 Services, shall submit to Congress a report that addresses
16 the effectiveness of section 505B of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring
18 that medicines used by children are tested and properly
19 labeled, including—

20 (1) the number and importance of drugs for
21 children that are being tested as a result of this pro-
22 vision and the importance for children, health care
23 providers, parents, and others of labeling changes
24 made as a result of such testing;

1 (2) the number and importance of drugs for
 2 children that are not being tested for their use not-
 3 withstanding the provisions of such section 505B,
 4 and possible reasons for the lack of testing; and

5 (3) the number of drugs for which testing is
 6 being done and labeling changes required, including
 7 the date labeling changes are made and which label-
 8 ing changes required the use of the dispute resolu-
 9 tion process established under such section 505B,
 10 together with a description of the outcomes of such
 11 process, including a description of the disputes and
 12 the recommendations of the Pediatric Advisory Com-
 13 mittee.

14 **SEC. 417. TECHNICAL CORRECTIONS.**

15 Section 505B(a)(2)(B)(ii) of the Federal Food, Drug,
 16 and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amend-
 17 ed by striking “one” and inserting “1”.

18 **Subtitle C—Pediatric Medical**
 19 **Devices**

20 **SEC. 421. SHORT TITLE.**

21 This subtitle may be cited as the “Pediatric Medical
 22 Device Safety and Improvement Act of 2007”.

1 **SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.**

2 Chapter V of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 351 et seq.) is amended by inserting after
4 section 515 the following:

5 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

6 “(a) NEW DEVICES.—

7 “(1) IN GENERAL.—A person that submits to
8 the Secretary an application under section 520(m),
9 or an application (or supplement to an application)
10 or a product development protocol under section
11 515, shall include in the application or protocol the
12 information described in paragraph (2).

13 “(2) REQUIRED INFORMATION.—The applica-
14 tion or protocol described in paragraph (1) shall in-
15 clude, with respect to the device for which approval
16 is sought and if readily available—

17 “(A) a description of any pediatric sub-
18 populations that suffer from the disease or con-
19 dition that the device is intended to treat, diag-
20 nose, or cure; and

21 “(B) the number of affected pediatric pa-
22 tients.

23 “(3) ANNUAL REPORT.—Not later than 18
24 months after the date of enactment of this section,
25 and annually thereafter, the Secretary shall submit
26 to the Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on En-
2 ergy and Commerce of the House of Representatives
3 a report that includes—

4 “(A) the number of devices approved in the
5 year preceding the year in which the report is
6 submitted, for which there is a pediatric sub-
7 population that suffers from the disease or con-
8 dition that the device is intended to treat, diag-
9 nose, or cure;

10 “(B) the number of devices approved in
11 the year preceding the year in which the report
12 is submitted, labeled for use in pediatric pa-
13 tients;

14 “(C) the number of pediatric devices ap-
15 proved in the year preceding the year in which
16 the report is submitted, exempted from a fee
17 pursuant to section 738(a)(2)(B)(v); and

18 “(D) the review time for each device de-
19 scribed in subparagraphs (A), (B), and (C).

20 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-
21 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-
22 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

23 “(1) IN GENERAL.—If the course of the disease
24 or condition and the effects of the device are suffi-
25 ciently similar in adults and pediatric patients, the

1 Secretary may conclude that adult data may be used
 2 to support a determination of a reasonable assur-
 3 ance of effectiveness in pediatric populations, as ap-
 4 propriate.

5 “(2) **EXTRAPOLATION BETWEEN SUBPOPULA-**
 6 **TIONS.**—A study may not be needed in each pedi-
 7 atric subpopulation if data from one subpopulation
 8 can be extrapolated to another subpopulation.

9 “(c) **PEDIATRIC SUBPOPULATION.**—In this section,
 10 the term ‘pediatric subpopulation’ has the meaning given
 11 the term in section 520(m)(6)(E)(ii).”.

12 **SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EX-**
 13 **EMPTION.**

14 (a) **IN GENERAL.**—Section 520(m) of the Federal
 15 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is
 16 amended—

17 (1) in paragraph (3), by striking “No” and in-
 18 serting “Except as provided in paragraph (6), no”;

19 (2) in paragraph (5)—

20 (A) by inserting “, if the Secretary has
 21 reason to believe that the requirements of para-
 22 graph (6) are no longer met,” after “public
 23 health”; and

24 (B) by adding at the end the following: “If
 25 the person granted an exemption under para-

1 graph (2) fails to demonstrate continued com-
2 pliance with the requirements of this sub-
3 section, the Secretary may suspend or withdraw
4 the exemption from the effectiveness require-
5 ments of sections 514 and 515 for a humani-
6 tarian device only after providing notice and an
7 opportunity for an informal hearing.”;

8 (3) by striking paragraph (6) and inserting the
9 following:

10 “(6)(A) Except as provided in subparagraph (D), the
11 prohibition in paragraph (3) shall not apply with respect
12 to a person granted an exemption under paragraph (2)
13 if each of the following conditions apply:

14 “(i)(I) The device with respect to which the ex-
15 emption is granted is intended for the treatment or
16 diagnosis of a disease or condition that occurs in pe-
17 diatric patients or in a pediatric subpopulation, and
18 such device is labeled for use in pediatric patients or
19 in a pediatric subpopulation in which the disease or
20 condition occurs.

21 “(II) The device was not previously approved
22 under this subsection for the pediatric patients or
23 the pediatric subpopulation described in subclause
24 (I) prior to the date of enactment of the Pediatric

1 Medical Device Safety and Improvement Act of
2 2007.

3 “(ii) During any calendar year, the number of
4 such devices distributed during that year does not
5 exceed the annual distribution number specified by
6 the Secretary when the Secretary grants such ex-
7 emption. The annual distribution number shall be
8 based on the number of individuals affected by the
9 disease or condition that such device is intended to
10 treat, diagnose, or cure, and of that number, the
11 number of individuals likely to use the device, and
12 the number of devices reasonably necessary to treat
13 such individuals. In no case shall the annual dis-
14 tribution number exceed the number identified in
15 paragraph (2)(A).

16 “(iii) Such person immediately notifies the Sec-
17 retary if the number of such devices distributed dur-
18 ing any calendar year exceeds the annual distribu-
19 tion number referred to in clause (ii).

20 “(iv) The request for such exemption is sub-
21 mitted on or before October 1, 2012.

22 “(B) The Secretary may inspect the records relating
23 to the number of devices distributed during any calendar
24 year of a person granted an exemption under paragraph

1 (2) for which the prohibition in paragraph (3) does not
2 apply.

3 “(C) A person may petition the Secretary to modify
4 the annual distribution number specified by the Secretary
5 under subparagraph (A)(ii) with respect to a device if ad-
6 ditional information on the number of individuals affected
7 by the disease or condition arises, and the Secretary may
8 modify such number but in no case shall the annual dis-
9 tribution number exceed the number identified in para-
10 graph (2)(A).

11 “(D) If a person notifies the Secretary, or the Sec-
12 retary determines through an inspection under subpara-
13 graph (B), that the number of devices distributed during
14 any calendar year exceeds the annual distribution number,
15 as required under subparagraph (A)(iii), and modified
16 under subparagraph (C), if applicable, then the prohibi-
17 tion in paragraph (3) shall apply with respect to such per-
18 son for such device for any sales of such device after such
19 notification.

20 “(E)(i) In this subsection, the term ‘pediatric pa-
21 tients’ means patients who are 21 years of age or younger
22 at the time of the diagnosis or treatment.

23 “(ii) In this subsection, the term ‘pediatric sub-
24 population’ means 1 of the following populations:

25 “(I) Neonates.

1 “(II) Infants.

2 “(III) Children.

3 “(IV) Adolescents.”; and

4 (4) by adding at the end the following:

5 “(7) The Secretary shall refer any report of an ad-
6 verse event regarding a device for which the prohibition
7 under paragraph (3) does not apply pursuant to para-
8 graph (6)(A) that the Secretary receives to the Office of
9 Pediatric Therapeutics, established under section 6 of the
10 Best Pharmaceuticals for Children Act (Public Law 107–
11 109)). In considering the report, the Director of the Office
12 of Pediatric Therapeutics, in consultation with experts in
13 the Center for Devices and Radiological Health, shall pro-
14 vide for periodic review of the report by the Pediatric Ad-
15 visory Committee, including obtaining any recommenda-
16 tions of such committee regarding whether the Secretary
17 should take action under this Act in response to the re-
18 port.”.

19 (b) REPORT.—Not later than January 1, 2012, the
20 Comptroller General of the United States shall submit to
21 the Committee on Health, Education, Labor, and Pen-
22 sions of the Senate and the Committee on Energy and
23 Commerce of the House of Representatives a report on
24 the impact of allowing persons granted an exemption
25 under section 520(m)(2) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a
2 device to profit from such device pursuant to section
3 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-
4 ed by subsection (a)), including—

5 (1) an assessment of whether such section
6 520(m)(6) (as amended by subsection (a)) has in-
7 creased the availability of pediatric devices for condi-
8 tions that occur in small numbers of children, in-
9 cluding any increase or decrease in the number of—

10 (A) exemptions granted under such section
11 520(m)(2) for pediatric devices; and

12 (B) applications approved under section
13 515 of such Act (21 U.S.C. 360e) for devices
14 intended to treat, diagnose, or cure conditions
15 that occur in pediatric patients or for devices
16 labeled for use in a pediatric population;

17 (2) the conditions or diseases the pediatric de-
18 vices were intended to treat or diagnose and the esti-
19 mated size of the pediatric patient population for
20 each condition or disease;

21 (3) the costs of the pediatric devices, based on
22 a survey of children's hospitals;

23 (4) the extent to which the costs of such devices
24 are covered by health insurance;

1 (5) the impact, if any, of allowing profit on ac-
2 cess to such devices for patients;

3 (6) the profits made by manufacturers for each
4 device that receives an exemption;

5 (7) an estimate of the extent of the use of the
6 pediatric devices by both adults and pediatric popu-
7 lations for a condition or disease other than the con-
8 dition or disease on the label of such devices;

9 (8) recommendations of the Comptroller Gen-
10 eral of the United States regarding the effectiveness
11 of such section 520(m)(6) (as amended by sub-
12 section (a)) and whether any modifications to such
13 section 520(m)(6) (as amended by subsection (a))
14 should be made;

15 (9) existing obstacles to pediatric device devel-
16 opment; and

17 (10) an evaluation of the demonstration grants
18 described in section 425, which shall include an eval-
19 uation of the number of pediatric medical devices—

20 (A) that have been or are being studied in
21 children; and

22 (B) that have been submitted to the Food
23 and Drug Administration for approval, clear-
24 ance, or review under such section 520(m) (as

1 amended by this Act) and any regulatory ac-
2 tions taken.

3 (c) GUIDANCE.—Not later than 180 days after the
4 date of enactment of this subtitle, the Commissioner of
5 Food and Drugs shall issue guidance for institutional re-
6 view committees on how to evaluate requests for approval
7 for devices for which a humanitarian device exemption
8 under section 520(m)(2) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

10 **SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.**

11 Section 402(b) of the Public Health Service Act (42
12 U.S.C. 282(b)) is amended—

13 (1) in paragraph (21), by striking “and” after
14 the semicolon at the end;

15 (2) in paragraph (22), by striking the period at
16 the end and inserting “; and”; and

17 (3) by inserting after paragraph (22) the fol-
18 lowing:

19 “(23) shall designate a contact point or office
20 to help innovators and physicians identify sources of
21 funding available for pediatric medical device devel-
22 opment.”.

23 **SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
24 **ATRIC DEVICE AVAILABILITY.**

25 (a) IN GENERAL.—

1 (1) REQUEST FOR PROPOSALS.—Not later than
2 90 days after the date of enactment of this subtitle,
3 the Secretary of Health and Human Services shall
4 issue a request for proposals for 1 or more grants
5 or contracts to nonprofit consortia for demonstration
6 projects to promote pediatric device development.

7 (2) DETERMINATION ON GRANTS OR CON-
8 TRACTS.—Not later than 180 days after the date the
9 Secretary of Health and Human Services issues a
10 request for proposals under paragraph (1), the Sec-
11 retary shall make a determination on the grants or
12 contracts under this section.

13 (b) APPLICATION.—A nonprofit consortium that de-
14 sires to receive a grant or contract under this section shall
15 submit an application to the Secretary of Health and
16 Human Services at such time, in such manner, and con-
17 taining such information as the Secretary may require.

18 (c) USE OF FUNDS.—A nonprofit consortium that re-
19 ceives a grant or contract under this section shall facilitate
20 the development, production, and distribution of pediatric
21 medical devices by—

22 (1) encouraging innovation and connecting
23 qualified individuals with pediatric device ideas with
24 potential manufacturers;

1 (2) mentoring and managing pediatric device
2 projects through the development process, including
3 product identification, prototype design, device devel-
4 opment, and marketing;

5 (3) connecting innovators and physicians to ex-
6 isting Federal and non-Federal resources, including
7 resources from the Food and Drug Administration,
8 the National Institutes of Health, the Small Busi-
9 ness Administration, the Department of Energy, the
10 Department of Education, the National Science
11 Foundation, the Department of Veterans Affairs,
12 the Agency for Healthcare Research and Quality,
13 and the National Institute of Standards and Tech-
14 nology;

15 (4) assessing the scientific and medical merit of
16 proposed pediatric device projects; and

17 (5) providing assistance and advice as needed
18 on business development, personnel training, proto-
19 type development, postmarket needs, and other ac-
20 tivities consistent with the purposes of this section.

21 (d) COORDINATION.—

22 (1) NATIONAL INSTITUTES OF HEALTH.—Each
23 consortium that receives a grant or contract under
24 this section shall—

1 (A) coordinate with the National Institutes
2 of Health's pediatric device contact point or of-
3 fice, designated under section 424; and

4 (B) provide to the National Institutes of
5 Health any identified pediatric device needs
6 that the consortium lacks sufficient capacity to
7 address or those needs in which the consortium
8 has been unable to stimulate manufacturer in-
9 terest.

10 (2) FOOD AND DRUG ADMINISTRATION.—Each
11 consortium that receives a grant or contract under
12 this section shall coordinate with the Commissioner
13 of Food and Drugs and device companies to facili-
14 tate the application for approval or clearance of de-
15 vices labeled for pediatric use.

16 (3) EFFECTIVENESS AND OUTCOMES.—Each
17 consortium that receives a grant or contract under
18 this section shall annually report to the Secretary of
19 Health and Human Services on—

20 (A) the effectiveness of activities conducted
21 under subsection (c);

22 (B) the impact of activities conducted
23 under subsection (c) on pediatric device devel-
24 opment; and

1 (C) the status of pediatric device develop-
 2 ment that has been facilitated by the consor-
 3 tium.

4 (e) AUTHORIZATION OF APPROPRIATIONS.—There
 5 are authorized to be appropriated to carry out this section
 6 \$6,000,000 for each of fiscal years 2008 through 2012.

7 **SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
 8 **PEUTICS AND PEDIATRIC ADVISORY COM-**
 9 **MITTEE.**

10 (a) IN GENERAL.—

11 (1) OFFICE OF PEDIATRIC THERAPEUTICS.—
 12 Section 6(b) of the Best Pharmaceuticals for Chil-
 13 dren Act (21 U.S.C. 393a(b)) is amended by insert-
 14 ing “, including increasing pediatric access to med-
 15 ical devices” after “pediatric issues”.

16 (2) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
 17 SEARCH.—

18 (A) IN GENERAL.—Not later than 270
 19 days after the date of enactment of this sub-
 20 title, the Office of Pediatric Therapeutics, in
 21 collaboration with the Director of the National
 22 Institutes of Health and the Director of the
 23 Agency for Healthcare Research and Quality,
 24 shall submit to the Committee on Health, Edu-
 25 cation, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the
2 House of Representatives a plan for expanding
3 pediatric medical device research and develop-
4 ment. In developing such plan, the Commis-
5 sioner of Food and Drugs shall consult with in-
6 dividuals and organizations with appropriate ex-
7 pertise in pediatric medical devices.

8 (B) CONTENTS.—The plan under subpara-
9 graph (A) shall include—

10 (i) the current status of federally
11 funded pediatric medical device research;

12 (ii) any gaps in such research, which
13 may include a survey of pediatric medical
14 providers regarding unmet pediatric med-
15 ical device needs, as needed; and

16 (iii) a research agenda for improving
17 pediatric medical device development and
18 Food and Drug Administration clearance
19 or approval of pediatric medical devices,
20 and for evaluating the short- and long-
21 term safety and effectiveness of pediatric
22 medical devices.

23 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14
24 of the Best Pharmaceuticals for Children Act (42 U.S.C.
25 284m note) is amended—

1 (1) in subsection (a), by inserting “(including
2 drugs and biological products) and medical devices”
3 after “therapeutics”; and

4 (2) in subsection (b)—

5 (A) in paragraph (1), by inserting “(in-
6 cluding drugs and biological products) and med-
7 ical devices” after “therapeutics”; and

8 (B) in paragraph (2)—

9 (i) in subparagraph (A), by striking
10 “and 505B” and inserting “505B, 510(k),
11 515, and 520(m)”;

12 (ii) by striking subparagraph (B) and
13 inserting the following:

14 “(B) identification of research priorities re-
15 lated to therapeutics (including drugs and bio-
16 logical products) and medical devices for pedi-
17 atric populations and the need for additional
18 diagnostics and treatments for specific pediatric
19 diseases or conditions; and”; and

20 (iii) in subparagraph (C), by inserting
21 “(including drugs and biological products)
22 and medical devices” after “therapeutics”.

1 **SEC. 427. POSTMARKET SURVEILLANCE.**

2 (a) POSTMARKET SURVEILLANCE.—Section 522 of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 360l) is amended—

5 (1) by striking subsection (a) and inserting the
6 following:

7 “(a) POSTMARKET SURVEILLANCE.—

8 “(1) IN GENERAL.—

9 “(A) CONDUCT.—The Secretary may by
10 order require a manufacturer to conduct
11 postmarket surveillance for any device of the
12 manufacturer that is a class II or class III de-
13 vice—

14 “(i) the failure of which would be rea-
15 sonably likely to have serious adverse
16 health consequences;

17 “(ii) that is expected to have signifi-
18 cant use in pediatric populations; or

19 “(iii) that is intended to be—

20 “(I) implanted in the human
21 body for more than 1 year; or

22 “(II) a life-sustaining or life-sup-
23 porting device used outside a device
24 user facility.

25 “(B) CONDITION.—The Secretary may
26 order a postmarket surveillance under subpara-

1 graph (A) as a condition to approval or clear-
 2 ance of a device described in subparagraph
 3 (A)(ii).

4 “(2) RULE OF CONSTRUCTION.—The provisions
 5 of paragraph (1) shall have no effect on authorities
 6 otherwise provided under the Act or regulations
 7 issued under this Act.”; and

8 (2) in subsection (b)—

9 (A) by striking “(b) SURVEILLANCE AP-
 10 PROVAL.—Each” and inserting the following:

11 “(b) SURVEILLANCE APPROVAL.—

12 “(1) IN GENERAL.—Each”;

13 (B) by striking “The Secretary, in con-
 14 sultation” and inserting “Except as provided in
 15 paragraph (2), the Secretary, in consultation”;

16 (C) by striking “Any determination” and
 17 inserting “Except as provided in paragraph (2),
 18 any determination”; and

19 (D) by adding at the end the following:

20 “(2) LONGER SURVEILLANCES FOR PEDIATRIC
 21 DEVICES.—The Secretary may by order require a
 22 prospective surveillance period of more than 36
 23 months with respect to a device that is expected to
 24 have significant use in pediatric populations if such
 25 period of more than 36 months is necessary in order

to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety of the device.”.

TITLE V—OTHER PROVISIONS

SEC. 501. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by section 241, is further amended by adding at the end the following:

“SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

“(a) DEFINITION.—In this section, the term ‘article’ means a paper, poster, abstract, book, book chapter, or other published writing.

“(b) POLICIES.—The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

“(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow and a con-

1 tractor who performs staff work, of the Food and Drug
2 Administration is required by the policies established
3 under subsection (b) to submit an article to the supervisor
4 of such officer or employee, or to some other official of
5 the Food and Drug Administration, for review and clear-
6 ance before such officer or employee may seek to publish
7 or present such an article at a conference, such officer
8 or employee shall submit such article for such review and
9 clearance not less than 30 days before submitting the arti-
10 cle for publication or presentation.

11 “(d) TIMING FOR REVIEW AND CLEARANCE.—The
12 supervisor or other reviewing official shall review such ar-
13 ticle and provide written clearance, or written clearance
14 on the condition of specified changes being made, to such
15 officer or employee not later than 30 days after such offi-
16 cer or employee submitted such article for review.

17 “(e) NON-TIMELY REVIEW.—If, 31 days after such
18 submission under subsection (c), the supervisor or other
19 reviewing official has not cleared or has not reviewed such
20 article and provided written clearance, such officer or em-
21 ployee may consider such article not to have been cleared
22 and may submit the article for publication or presentation
23 with an appropriate disclaimer as specified in the policies
24 established under subsection (b).”.

1 **SEC. 502. TECHNICAL AMENDMENTS.**

2 The Public Health Service Act (42 U.S.C. 201 et
3 seq.) is amended—

4 (1) in section 319C–2(j)(3)(B), by striking
5 “section 319C–1(h)” and inserting “section 319C–
6 1(i)”;

7 (2) in section 402(b)(4), by inserting “minority
8 and other” after “reducing”;

9 (3) in section 403(a)(4)(C)(iv)(III), by inserting
10 “and post doctoral training funded through investi-
11 gator-initiated research grant awards” before the
12 semicolon; and

13 (4) in section 403C(a)—

14 (A) in the matter preceding paragraph (1),
15 by inserting “graduate students supported by
16 NIH for” after “with respect to”;

17 (B) in paragraph (1), by inserting “such”
18 after “percentage of”; and

19 (C) in paragraph (2), by inserting “(not
20 including any leaves of absence)” after “average
21 time”.

22 **SEC. 503. SEVERABILITY CLAUSE.**

23 If any provision of this Act, an amendment made this
24 Act, or the application of such provision or amendment
25 to any person or circumstance is held to be unconstitu-
26 tional, the remainder of this Act, the amendments made

1 by this Act, and the application of the provisions of such
2 to any person or circumstances shall not be affected there-
3 by.

4 **SEC. 504. SENSE OF THE SENATE WITH RESPECT TO FOL-**
5 **LOW-ON BIOLOGICS.**

6 (a) FINDINGS.—The Senate finds the following:

7 (1) The Food and Drug Administration has
8 stated that it requires legislative authority to review
9 follow-on biologics.

10 (2) Business, consumer, and government pur-
11 chasers require competition and choice to ensure
12 more affordable prescription drug options.

13 (3) Well-constructed policies that balance the
14 needs of innovation and affordability have broad bi-
15 partisan support.

16 (b) SENSE OF THE SENATE.—It is the sense of the
17 Senate that legislation should be enacted to—

18 (1) provide the Food and Drug Administration
19 with the authority and flexibility to approve bio-
20 pharmaceuticals subject to an abbreviated approval
21 pathway;

22 (2) ensure that patient safety remains para-
23 mount in the system;

24 (3) establish a regulatory pathway that is effi-
25 cient, effective, and scientifically-grounded and that

1 also includes measures to ensure timely resolution of
 2 patent disputes; and

3 (4) provide appropriate incentives to facilitate
 4 the research and development of innovative bio-
 5 pharmaceuticals.

6 **SEC. 505. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
 7 **FOR TROPICAL DISEASES.**

8 Subchapter A of chapter V of the Federal Food,
 9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 10 ed by adding at the end the following:

11 **“SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
 12 **FOR TROPICAL DISEASES.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) AIDS.—The term ‘AIDS’ means the ac-
 15 quired immune deficiency syndrome.

16 “(2) AIDS DRUG.—The term ‘AIDS drug’
 17 means a drug indicated for treating HIV.

18 “(3) HIV.—The term ‘HIV’ means the human
 19 immunodeficiency virus, the pathogen that causes
 20 AIDS.

21 “(4) NEGLECTED OR TROPICAL DISEASE.—The
 22 term ‘neglected or tropical disease’ means—

23 “(A) HIV, malaria, tuberculosis, and re-
 24 lated diseases; or

“(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

“(5) PRIORITY REVIEW.—The term ‘priority review’, with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

“(6) PRIORITY REVIEW VOUCHER.—The term ‘priority review voucher’ means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

“(7) TROPICAL DISEASE PRODUCT.—The term ‘tropical disease product’ means a product that—

1 “(A) is a new drug, antibiotic drug, bio-
2 logical product, vaccine, device, diagnostic, or
3 other tool for treatment of a neglected or trop-
4 ical disease; and

5 “(B) is approved by the Secretary for use
6 in the treatment of a neglected or tropical dis-
7 ease.

8 “(b) PRIORITY REVIEW VOUCHER.—

9 “(1) IN GENERAL.—The Secretary shall award
10 a priority review voucher to the sponsor of a tropical
11 disease product upon approval by the Secretary of
12 such tropical disease product.

13 “(2) TRANSFERABILITY.—The sponsor of a
14 tropical disease product that receives a priority re-
15 view voucher under this section may transfer (in-
16 cluding by sale) the entitlement to such voucher to
17 a sponsor of a new drug for which an application
18 under section 505(b)(1) will be submitted after the
19 date of the approval of the tropical disease product.

20 “(3) LIMITATION.—A sponsor of a tropical dis-
21 ease product may not receive a priority review
22 voucher under this section if the tropical disease
23 product was approved by the Secretary prior to the
24 date of enactment of this section.

25 “(c) PRIORITY REVIEW USER FEE.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a user fee program under which a sponsor of a
3 drug that is the subject of a priority review voucher
4 shall pay to the Secretary a fee determined under
5 paragraph (2). Such fee shall be in addition to any
6 fee required to be submitted by the sponsor under
7 chapter VII.

8 “(2) FEE AMOUNT.—The amount of the pri-
9 ority review user fee shall be determined each fiscal
10 year by the Secretary and based on the anticipated
11 costs to the Secretary of implementing this section.

12 “(3) ANNUAL FEE SETTING.—The Secretary
13 shall establish, before the beginning of each fiscal
14 year beginning after September 30, 2007, for that
15 fiscal year, the amount of the priority review user
16 fee.

17 “(4) PAYMENT.—

18 “(A) IN GENERAL.—The fee required by
19 this subsection shall be due upon the filing of
20 the new drug application under section
21 505(b)(1) for which the voucher is used.

22 “(B) COMPLETE APPLICATION.—An appli-
23 cation described under subparagraph (A) for
24 which the sponsor requests the use of a priority
25 review voucher shall be considered incomplete if

1 the fee required by this subsection is not in-
 2 cluded in such application.

3 “(5) OFFSETTING COLLECTIONS.—Fees col-
 4 lected pursuant to this subsection for any fiscal
 5 year—

6 “(A) shall be deposited and credited as off-
 7 setting collections to the account providing ap-
 8 propriations to the Food and Drug Administra-
 9 tion; and

10 “(B) shall not be collected for any fiscal
 11 year except to the extent provided in advance in
 12 appropriation Acts.”.

13 **SEC. 506. CITIZENS PETITIONS AND PETITIONS FOR STAY**
 14 **OF AGENCY ACTION.**

15 Section 505 of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 355), as amended by this Act, is amended
 17 by adding at the end the following:

18 “(s) CITIZEN PETITIONS AND PETITIONS FOR STAY
 19 OF AGENCY ACTION.—

20 “(1) IN GENERAL.—

21 “(A) NO DELAY OF CONSIDERATION OR
 22 APPROVAL.—

23 “(i) IN GENERAL.—With respect to a
 24 pending application submitted under sub-
 25 section (b)(2) or (j), if a petition is sub-

mitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

“(ii) NO DELAY OF CONSIDERATION OR APPROVAL.—Except as provided in clause (iii), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

“(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

“(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary

1 under subparagraph (A)(iii) that a delay is nec-
2 essary to protect the public health the following
3 shall apply:

4 “(i) Not later than 5 days after mak-
5 ing such determination, the Secretary shall
6 publish on the Internet website of the
7 Food and Drug Administration a detailed
8 statement providing the reasons underlying
9 the determination. The detailed statement
10 shall include a summary of the petition
11 and comments and supplements, the spe-
12 cific substantive issues that the petition
13 raises which need to be considered prior to
14 approving a pending application submitted
15 under subsection (b)(2) or (j), and any
16 clarifications and additional data that is
17 needed by the Secretary to promptly review
18 the petition.

19 “(ii) Not later than 10 days after
20 making such determination, the Secretary
21 shall provide notice to the sponsor of the
22 pending application submitted under sub-
23 section (b)(2) or (j) and provide an oppor-
24 tunity for a meeting with appropriate staff

1 as determined by the Commissioner to dis-
2 cuss the determination.

3 “(2) TIMING OF FINAL AGENCY ACTION ON PE-
4 TITIONS.—

5 “(A) IN GENERAL.—Notwithstanding a de-
6 termination made by the Secretary under para-
7 graph (1)(A)(iii), the Secretary shall take final
8 agency action with respect to a petition not
9 later than 180 days of submission of that peti-
10 tion unless the Secretary determines, prior to
11 the date that is 180 days after the date of sub-
12 mission of the petition, that a delay is necessary
13 to protect the public health.

14 “(B) DETERMINATION OF DELAY.—With
15 respect to a determination by the Secretary
16 under subparagraph (A) that a delay is nec-
17 essary to protect the public health the following
18 shall apply:

19 “(i) Not later than 5 days after mak-
20 ing the determination under subparagraph
21 (A), the Secretary shall publish on the
22 Internet website of the Food and Drug Ad-
23 ministration a detailed statement providing
24 the reasons underlying the determination.
25 The detailed statement should include the

1 state of the review of the petition, the spe-
2 cific outstanding issues that still need to
3 be resolved, a proposed timeframe to re-
4 solve the issues, and any additional infor-
5 mation that has been requested by the Sec-
6 retary of the petitioner or needed by the
7 Secretary in order to resolve the petition
8 and not further delay an application filed
9 under subsection (b)(2) or (j).

10 “(ii) Not later than 10 days after
11 making the determination under subpara-
12 graph (A), the Secretary shall provide no-
13 tice to the sponsor of the pending applica-
14 tion submitted under subsection (b)(2) or
15 (j) and provide an opportunity for a meet-
16 ing with appropriate staff as determined
17 by the Commissioner to discuss the deter-
18 mination.

19 “(3) VERIFICATIONS.—

20 “(A) PETITIONS FOR REVIEW.—The Sec-
21 retary shall not accept a petition for review un-
22 less it is signed and contains the following
23 verification: ‘I certify that, to my best knowl-
24 edge and belief: (a) this petition includes all in-
25 formation and views upon which the petition re-

1 lies; (b) this petition includes representative
2 data and/or information known to the petitioner
3 which are unfavorable to the petition; and (c)
4 information upon which I have based the action
5 requested herein first became known to the
6 party on whose behalf this petition is filed on
7 or about _____. I received or
8 expect to receive payments, including cash and
9 other forms of consideration, from the following
10 persons or organizations to file this petition:
11 _____. I verify under penalty of
12 perjury that the foregoing is true and correct.’,
13 with the date of the filing of such petition and
14 the signature of the petitioner inserted in the
15 first and second blank space, respectively.

16 “(B) SUPPLEMENTAL INFORMATION.—The
17 Secretary shall not accept for review any sup-
18 plemental information or comments on a peti-
19 tion unless the party submitting such informa-
20 tion or comments does so in written form and
21 that the subject document is signed and con-
22 tains the following verification: ‘I certify that,
23 to my best knowledge and belief: (a) I have not
24 intentionally delayed submission of this docu-
25 ment or its contents; and (b) the information

1 upon which I have based the action requested
2 herein first became known to me on or about
3 _____. I received or expect to
4 receive payments, including cash and other
5 forms of consideration, from the following per-
6 sons or organizations to submit this information
7 or its contents: _____. I verify under pen-
8 alty of perjury that the foregoing is true and
9 correct.’, with the date of the submission of
10 such document and the signature of the peti-
11 tioner inserted in the first and second blank
12 space, respectively.

13 “(4) ANNUAL REPORT ON DELAYS IN APPROV-
14 ALS PER PETITION.—The Secretary shall annually
15 submit to the Congress a report that specifies—

16 “(A) the number of applications under
17 subsection (b)(2) and (j) that were approved
18 during the preceding 1-year period;

19 “(B) the number of petitions that were
20 submitted during such period;

21 “(C) the number of applications whose ef-
22 fective dates were delayed by petitions during
23 such period and the number of days by which
24 the applications were so delayed; and

1 “(D) the number of petitions that were
2 filed under this subsection that were deemed by
3 the Secretary under paragraph (1)(A)(iii) to re-
4 quire delaying an application under subsection
5 (b)(2) or (j) and the number of days by which
6 the applications were so delayed.

7 “(5) EXCEPTION.—This subsection does not
8 apply to a petition that is made by the sponsor of
9 the application under subsection (b)(2) or (j) and
10 that seeks only to have the Secretary take or refrain
11 from taking any form of action with respect to that
12 application.

13 “(6) REPORT BY INSPECTOR GENERAL.—The
14 Office of Inspector General of the Department of
15 Health and Human Services shall issue a report not
16 later than 2 years after the date of enactment of
17 this subsection evaluating evidence of the compliance
18 of the Food and Drug Administration with the re-
19 quirement that the consideration by the Secretary of
20 petitions that do not raise public health concerns re-
21 main separate and apart from the review and ap-
22 proval of an application submitted under subsection
23 (b)(2) or (j).

24 “(7) DEFINITION.—For purposes of this sub-
25 section, the term ‘petition’ includes any request for

1 an action described in paragraph (1)(A)(i) to the
2 Secretary, without regard to whether the request is
3 characterized as a petition.”.

4 **SEC. 507. PUBLICATION OF ANNUAL REPORTS.**

5 (a) IN GENERAL.—The Commissioner on Food and
6 Drugs shall annually submit to Congress and publish on
7 the Internet website of the Food and Drug Administra-
8 tion, a report concerning the results of the Administra-
9 tion’s pesticide residue monitoring program, that in-
10 cludes—

11 (1) information and analysis similar to that
12 contained in the report entitled “Food and Drug Ad-
13 ministration Pesticide Program Residue Monitoring
14 2003” as released in June of 2005;

15 (2) based on an analysis of previous samples,
16 an identification of products or countries (for im-
17 ports) that require special attention and additional
18 study based on a comparison with equivalent prod-
19 ucts manufactured, distributed, or sold in the United
20 States (including details on the plans for such addi-
21 tional studies), including in the initial report (and
22 subsequent reports as determined necessary) the re-
23 sults and analysis of the Ginseng Dietary Supple-
24 ments Special Survey as described on page 13 of the

1 report entitled “Food and Drug Administration Pes-
2 ticide Program Residue Monitoring 2003”;

3 (3) information on the relative number of inter-
4 state and imported shipments of each tested com-
5 modity that were sampled, including recommenda-
6 tions on whether sampling is statistically significant,
7 provides confidence intervals or other related statis-
8 tical information, and whether the number of sam-
9 ples should be increased and the details of any plans
10 to provide for such increase; and

11 (4) a description of whether certain commod-
12 ities are being improperly imported as another com-
13 modity, including a description of additional steps
14 that are being planned to prevent such smuggling.

15 (b) INITIAL REPORTS.—Annual reports under sub-
16 section (a) for fiscal years 2004 through 2006 may be
17 combined into a single report, by not later than June 1,
18 2008, for purposes of publication under subsection (a).
19 Thereafter such reports shall be completed by June 1 of
20 each year for the data collected for the year that was 2-
21 years prior to the year in which the report is published.

22 (c) MEMORANDUM OF UNDERSTANDING.—The Com-
23 missioner of Food and Drugs, the Administrator of the
24 Food Safety and Inspection Service, the Department of
25 Commerce, and the head of the Agricultural Marketing

1 Service shall enter into a memorandum of understanding
 2 to permit inclusion of data in the reports under subsection
 3 (a) relating to testing carried out by the Food Safety and
 4 Inspection Service and the Agricultural Marketing Service
 5 on meat, poultry, eggs, and certain raw agricultural prod-
 6 ucts, respectively.

7 **SEC. 508. HEAD START ACT AMENDMENT IMPOSING PAREN-**
 8 **TAL CONSENT REQUIREMENT FOR NON-**
 9 **EMERGENCY INTRUSIVE PHYSICAL EXAMINA-**
 10 **TIONS.**

11 The Head Start Act (42 U.S.C. 9831 et seq.) is
 12 amended by adding at the end the following:

13 **“SEC. 657A. PARENTAL CONSENT REQUIREMENT FOR NON-**
 14 **EMERGENCY INTRUSIVE PHYSICAL EXAMINA-**
 15 **TIONS.**

16 “(a) IN GENERAL.—A Head Start agency shall ob-
 17 tain written parental consent before administration of any
 18 nonemergency intrusive physical examination of a child in
 19 connection with participation in a program under this sub-
 20 chapter.

21 “(b) DEFINITION.—The term ‘nonemergency intru-
 22 sive physical examination’ means, with respect to a child,
 23 a physical examination that—

1 “(1) is not immediately necessary to protect the
2 health or safety of the child involved or the health
3 or safety of another individual; and

4 “(2) requires incision or is otherwise invasive,
5 or involves exposure of private body parts.

6 “(c) **RULE OF CONSTRUCTION.**—Nothing in this sec-
7 tion shall be construed to prohibit agencies from using es-
8 tablished methods, for handling cases of suspected or
9 known child abuse and neglect, that are in compliance
10 with applicable Federal, State, or tribal law.”.

11 **SEC. 509. SAFETY OF FOOD ADDITIVES.**

12 Not later than 90 days after the date of enactment
13 of this Act, the Food and Drug Administration shall issue
14 a report on the question of whether substances used to
15 preserve the appearance of fresh meat may create any
16 health risks, or mislead consumers.

17 **SEC. 510. IMPROVING GENETIC TEST SAFETY AND QUALITY.**

18 Not later than 30 days after the date of enactment
19 of this Act, the Secretary shall enter into a contract with
20 the Institute of Medicine to conduct a study to assess the
21 overall safety and quality of genetic tests and prepare a
22 report that includes recommendations to improve Federal
23 oversight and regulation of genetic tests. Such study shall
24 take into consideration relevant reports by the Secretary’s
25 Advisory Committee on Genetic Testing and other groups

1 and shall be completed not later than 1 year after the date
2 on which the Secretary entered into such contract.

3 **SEC. 511. ORPHAN DISEASE TREATMENT IN CHILDREN.**

4 (a) FINDING.—The Senate finds that parents of chil-
5 dren suffering from rare genetic diseases known as orphan
6 diseases face multiple obstacles in obtaining safe and ef-
7 fective treatment for their children due mainly to the fact
8 that many Food and Drug Administration-approved drugs
9 used in the treatment of orphan diseases in children may
10 not be approved for pediatric indications.

11 (b) SENSE OF THE SENATE.—It is the sense of the
12 Senate that the Food and Drug Administration should
13 enter into a contract with the Institute of Medicine for
14 the conduct of a study concerning measures that may be
15 taken to improve the likelihood that Food and Drug Ad-
16 ministration-approved drugs that are safe and effective in
17 treating children with orphan diseases are made available
18 and affordable for pediatric indications.

19 **SEC. 512. COLOR CERTIFICATION REPORTS.**

20 Section 721 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 379e) is amended by adding at the end
22 the following:

23 “(g) COLOR CERTIFICATION REPORTS.—Not later
24 than—

1 “(1) 90 days after the close of a fiscal year in
2 which color certification fees are collected, the Sec-
3 retary shall submit to Congress a performance re-
4 port for such fiscal year on the number of batches
5 of color additives approved, the average turn around
6 time for approval, and quantifiable goals for improv-
7 ing laboratory efficiencies; and

8 “(2) 120 days after the close of a fiscal year in
9 which color certification fees are collected, the Sec-
10 retary shall submit to Congress a financial report
11 for such fiscal year that includes all fees and ex-
12 penses of the color certification program, the balance
13 remaining in the fund at the end of the fiscal year,
14 and anticipated costs during the next fiscal year for
15 equipment needs and laboratory improvements of
16 such program.”.

17 **SEC. 513. PROHIBITION ON IMPORTATION FROM A FOR-**
18 **EIGN FOOD FACILITY THAT DENIES ACCESS**
19 **TO FOOD INSPECTORS.**

20 Notwithstanding any other provision of law, no food
21 product may be imported into the United States that is
22 the product of a foreign facility registered under section
23 415 of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 350d) that refuses to permit United States inspec-

1 tors, upon request, to inspect such facility or that unduly
2 delays access to United States inspectors.

3 **SEC. 514. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

4 Notwithstanding any other provision of this Act, the
5 requirement that the Secretary of Health and Human
6 Services certify that the implementation of the title of this
7 Act relating to the Importation of Prescription Drugs will
8 pose no additional risk to the public's health and safety
9 and will result in a significant reduction in the cost of
10 covered products to the American consumer shall not
11 apply to the requirement that the Secretary require that
12 the packaging of any prescription drug incorporates—

13 (1) not later than 18 months after the date of
14 enactment of this Act, a standardized numerical
15 identifier (which, to the extent practicable, shall be
16 harmonized with international consensus standards
17 for such an identifier) unique to each package of
18 such drug, applied at the point of manufacturing
19 and repackaging (in which case the numerical identi-
20 fier shall be linked to the numerical identifier ap-
21 plied at the point of manufacturing); and

22 (2) not later than 24 months after the date of
23 enactment of this Act for the 50 prescription drugs
24 with the highest dollar volume of sales in the United
25 States, based on the calendar year that ends of De-

1 cember 31, 2007, and, not later than 30 months
2 after the date of enactment of this Act for all other
3 prescription drugs—

4 (A) overt optically variable counterfeit-re-
5 sistant technologies that—

6 (i) are visible to the naked eye, pro-
7 viding for visual identification of product
8 authenticity without the need for readers,
9 microscopes, lighting devices, or scanners;

10 (ii) are similar to that used by the
11 Bureau of Engraving and Printing to se-
12 cure United States currency;

13 (iii) are manufactured and distributed
14 in a highly secure, tightly controlled envi-
15 ronment; and

16 (iv) incorporate additional layers of
17 nonvisible covert security features up to
18 and including forensic capability; or

19 (B) technologies that have a function of se-
20 curity comparable to that described in subpara-
21 graph (A), as determined by the Secretary.

22 **SEC. 515. ENHANCED AQUACULTURE AND SEAFOOD IN-**
23 **SPECTION.**

24 (a) FINDINGS.—Congress finds the following:

1 (1) In 2007, there has been an overwhelming
2 increase in the volume of aquaculture and seafood
3 that has been found to contain substances that are
4 not approved for use in food in the United States.

5 (2) As of May 2007, inspection programs are
6 not able to satisfactorily accomplish the goals of en-
7 suring the food safety of the United States.

8 (3) To protect the health and safety of con-
9 sumers in the United States, the ability of the Sec-
10 retary of Health and Human Services to perform in-
11 spection functions must be enhanced.

12 (b) HEIGHTENED INSPECTIONS.—The Secretary of
13 Health and Human Services (referred to in this section
14 as the “Secretary”) is authorized to, by regulation, en-
15 hance, as necessary, the inspection regime of the Food and
16 Drug Administration for aquaculture and seafood, con-
17 sistent with obligations of the United States under inter-
18 national agreements and United States law.

19 (c) REPORT TO CONGRESS.—Not later than 90 days
20 after the date of enactment of this Act, the Secretary shall
21 submit to Congress a report that—

22 (1) describes the specifics of the aquaculture
23 and seafood inspection program;

24 (2) describes the feasibility of developing a
25 traceability system for all catfish and seafood prod-

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

15 SEC. 516. SENSE OF THE SENATE REGARDING CERTAIN
16 PATENT INFRINGEMENTS.

(1) Innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

•S 1082 ES

1 (3) In order to maintain the global competitive-
2 ness of the United States, the United States Trade
3 Representative's Office of Intellectual Property and
4 Innovation develops and implements trade policy in
5 support of vital American innovations, including in-
6 novation in the pharmaceutical and medical tech-
7 nology industries.

8 (4) The United States Trade Representative
9 also provides trade policy leadership and expertise
10 across the full range of interagency initiatives to en-
11 hance protection and enforcement of intellectual
12 property rights.

13 (5) Strong and fair intellectual property protec-
14 tion, including patent, copyright, trademark, and
15 data protection plays an integral role in fostering
16 economic growth and development and ensuring pa-
17 tient access to the most effective medicines around
18 the world.

19 (6) There are concerns that certain countries
20 have engaged in unfair price manipulation and abuse
21 of compulsory licensing. Americans bear the major-
22 ity of research and development costs for the world,
23 which could undermine the value of existing United
24 States pharmaceutical patents and could impede ac-
25 cess to important therapies.

1 (7) There is a growing global threat of counter-
2 feit medicines and increased need for the United
3 States Trade Representative and other United
4 States agencies to use available trade policy meas-
5 ures to strengthen laws and enforcement abroad to
6 prevent harm to United States patients and patients
7 around the world.

8 (b) SENSE OF THE SENATE.—It is the sense of the
9 Senate that—

10 (1) the United States Trade Representative
11 should use all the tools at the disposal of the Trade
12 Representative to address violations and other con-
13 cerns with intellectual property, including through—

14 (A) bilateral engagement with United
15 States trading partners;

16 (B) transparency and balance of the an-
17 nual “Special 301” review and reviews of com-
18 pliance with the intellectual property require-
19 ments of countries with respect to which the
20 United States grants trade preferences;

21 (C) negotiation of responsible and fair in-
22 tellectual property provisions as part of bilateral
23 and regional trade agreements; and

24 (D) multilateral engagement through the
25 World Trade Organization (WTO); and

1 (2) the United States Trade Representative
2 should develop and submit to Congress a strategic
3 plan to address the problem of countries that in-
4 fringe upon American pharmaceutical intellectual
5 property rights and the problem of countries that
6 engage in price manipulation.

7 **SEC. 517. CONSULTATION REGARDING GENETICALLY ENGI-**
8 **NEERED SEAFOOD PRODUCTS.**

9 The Commissioner of Food and Drugs shall consult
10 with the Assistant Administrator of the National Marine
11 Fisheries Service of the National Oceanic and Atmos-
12 pheric Administration to produce a report on any environ-
13 mental risks associated with genetically engineered sea-
14 food products, including the impact on wild fish stocks.

15 **SEC. 518. REPORT ON THE MARKETING OF CERTAIN CRUS-**
16 **TACEANS.**

17 Not later than 30 days after the date of enactment
18 of this Act, the Secretary of Health and Human Services,
19 in consultation with the Secretary of Commerce, shall sub-
20 mit to the Health, Education, Labor, and Pensions Com-
21 mittee and the Committee on Commerce, Science, and
22 Transportation of the Senate, a report on the differences
23 between taxonomy of species of lobster in the subfamily
24 Nephropinae, and species of langostino, specifically from
25 the infraorder Caridea or Anomura. This report shall also

1 describe the differences in consumer perception of such
2 species, including such factors as taste, quality, and value
3 of the species.

4 **SEC. 519. CIVIL PENALTIES; DIRECT-TO-CONSUMER ADVER-**
5 **TISEMENT.**

6 (a) CIVIL PENALTIES.—Section 303 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-
8 ed by adding at the end the following:

9 “(g)(1) Any applicant (as such term is used in section
10 505(o)) who disseminates a direct-to-consumer advertise-
11 ment for a prescription drug that is false or misleading
12 and a violation of section 502(n) shall be liable to the
13 United States for a civil penalty in an amount not to ex-
14 ceed \$150,000 for the first such violation in any 3-year
15 period, and not to exceed \$300,000 for each subsequent
16 violation committed after the applicant has been penalized
17 under this paragraph any time in the preceding 3-year pe-
18 riod. For the purposes of this paragraph, repeated dis-
19 semination of the same or similar advertisement prior to
20 the receipt of the written notice referred to in paragraph
21 (2) for such advertisements shall be considered as 1 viola-
22 tion.

23 “(2) A civil penalty under paragraph (1) shall be as-
24 sessed by the Secretary by an order made on the record
25 after providing written notice to the applicant to be as-

1 assessed a civil penalty and an opportunity for a hearing
2 in accordance with this paragraph and section 554 of title
3 5, United States Code. If upon receipt of the written no-
4 tice, the applicant to be assessed a civil penalty objects
5 and requests a hearing, then in the course of any inves-
6 tigation related to such hearing, the Secretary may issue
7 subpoenas requiring the attendance and testimony of wit-
8 nesses and the production of evidence that relates to the
9 matter under investigation, including information per-
10 taining to the factors described in paragraph (3).

11 “(3) Upon the request of the applicant to be assessed
12 a civil penalty, the Secretary, in determining the amount
13 of a civil penalty, shall take into account the nature, cir-
14 cumstances, extent, and gravity of the violation or viola-
15 tions, including the following factors:

16 “(A) Whether the applicant submitted the ad-
17 vertisement or a similar advertisement for review
18 under section 736A.

19 “(B) Whether the applicant submitted the ad-
20 vertisement for prereview if required under section
21 505(o)(5)(D).

22 “(C) Whether, after submission of the adver-
23 tisement as described in subparagraph (A) or (B),
24 the applicant disseminated the advertisement before
25 the end of the 45-day comment period.

1 “(D) Whether the applicant failed to incor-
2 porate any comments made by the Secretary with re-
3 gard to the advertisement or a similar advertisement
4 into the advertisement prior to its dissemination.

5 “(E) Whether the applicant ceased distribution
6 of the advertisement upon receipt of the written no-
7 tice referred to in paragraph (2) for such advertise-
8 ment.

9 “(F) Whether the applicant had the advertise-
10 ment reviewed by qualified medical, regulatory, and
11 legal reviewers prior to its dissemination.

12 “(G) Whether the violations were material.

13 “(H) Whether the applicant who created the
14 advertisement acted in good faith.

15 “(I) Whether the applicant who created the ad-
16 vertisement has been assessed a civil penalty under
17 this provision within the previous 1-year period.

18 “(J) The scope and extent of any voluntary,
19 subsequent remedial action by the applicant.

20 “(K) Such other matters, as justice may re-
21 quire.

22 “(4)(A) Subject to subparagraph (B), no applicant
23 shall be required to pay a civil penalty under paragraph
24 (1) if the applicant submitted the advertisement to the

1 Secretary and disseminated such advertisement after in-
2 corporating any comment received from the Secretary.

3 “(B) The Secretary may retract or modify any prior
4 comments the Secretary has provided to an advertisement
5 submitted to the Secretary based on new information or
6 changed circumstances, so long as the Secretary provides
7 written notice to the applicant of the new views of the Sec-
8 retary on the advertisement and provides a reasonable
9 time for modification or correction of the advertisement
10 prior to seeking any civil penalty under paragraph (1).

11 “(5) The Secretary may compromise, modify, remit,
12 with or without conditions, any civil penalty which may
13 be assessed under paragraph (1). The amount of such pen-
14 alty, when finally determined, or the amount charged upon
15 in compromise, may be deducted from any sums owned
16 by the United States to the applicant charged.

17 “(6) Any applicant who requested, in accordance with
18 paragraph (2), a hearing with respect to the assessment
19 of a civil penalty and who is aggrieved by an order assess-
20 ing a civil penalty, may file a petition for de novo judicial
21 review of such order with the United States Court of Ap-
22 peals for the District of Columbia Circuit or for any other
23 circuit in which such applicant resides or transacts busi-
24 ness. Such a petition may only be filed within the 60-day

1 period beginning on the date the order making such as-
2 sessments was issued.

3 “(7) If any applicant fails to pay an assessment of
4 a civil penalty—

5 “(A) after the order making the assessment be-
6 comes final, and if such applicant does not file a pe-
7 tition for judicial review of the order in accordance
8 with paragraph (6); or

9 “(B) after a court in an action brought under
10 paragraph (6) has entered a final judgment in favor
11 of the Secretary,

12 the Attorney General shall recover the amount assessed
13 (plus interest at currently prevailing rates from the date
14 of the expiration of the 60-day period referred to in para-
15 graph (6) or date of such final judgment, as the case may
16 be) in an action brought in any appropriate district court
17 of the United States. In such an action, the validity,
18 amount, and appropriateness of such penalty shall not be
19 subject to review.”.

20 (b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

21 (1) IN GENERAL.—Section 502(n) of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 352(n)) is amended by inserting after the first sen-
24 tence the following: “In the case of an advertisement
25 for a prescription drug presented directly to con-

sumers in television or radio format that states the name of the drug and its conditions of use, the major statement relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.”.

(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by paragraph (1)) is presented in the manner required under such section.

SEC. 520. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall determine—

1 (1) whether the labeling requirements for in-
2 door tanning devices, including the positioning re-
3 quirements, provide sufficient information to con-
4 sumers regarding the risks that the use of such de-
5 vices pose for the development of irreversible damage
6 to the eyes and skin, including skin cancer; and

7 (2)(A) whether modifying the warning label re-
8 quired on tanning beds to read, “Ultraviolet radi-
9 ation can cause skin cancer”, or any other additional
10 warning, would communicate the risks of indoor tan-
11 ning more effectively; or

12 (B) whether there is no warning that would be
13 capable of adequately communicating such risks.

14 (b) CONSUMER TESTING.—In making the determina-
15 tions under subsection (a), the Secretary shall conduct ap-
16 propriate consumer testing, using the best available meth-
17 ods for determining consumer understanding of label
18 warnings.

19 (c) PUBLIC HEARINGS; PUBLIC COMMENT.—The
20 Secretary shall hold public hearings and solicit comments
21 from the public in making the determinations under sub-
22 section (a).

23 (d) REPORT.—Not later than 1 year after the date
24 of the enactment of this Act, the Secretary shall submit
25 to the Congress a report that provides the determinations

1 under subsection (a). In addition, the Secretary shall in-
2 clude in the report the measures being implemented by
3 the Secretary to significantly reduce the risks associated
4 with indoor tanning devices.

5 **TITLE VI—FOOD SAFETY**

6 **SEC. 601. FINDINGS.**

7 (a) FINDINGS.—Congress finds that—

8 (1) the safety and integrity of the United
9 States food supply is vital to the public health, to
10 public confidence in the food supply, and to the suc-
11 cess of the food sector of the Nation’s economy;

12 (2) illnesses and deaths of individuals and com-
13 panion animals caused by contaminated food—

14 (A) have contributed to a loss of public
15 confidence in food safety; and

16 (B) have caused significant economic losses
17 to manufacturers and producers not responsible
18 for contaminated food items;

19 (3) the task of preserving the safety of the food
20 supply of the United States faces tremendous pres-
21 sures with regard to—

22 (A) emerging pathogens and other con-
23 taminants and the ability to detect all forms of
24 contamination; and

1 (B) an increasing volume of imported food
2 from a wide variety of countries; and

3 (C) a shortage of adequate resources for
4 monitoring and inspection;

5 (4) the United States is increasing the amount
6 of food that it imports such that—

7 (A) from 2003 to the present, the value of
8 food imports has increased from
9 \$45,600,000,000 to \$64,000,000,000; and

10 (B) imported food accounts for 13 percent
11 of the average Americans diet including 31 per-
12 cent of fruits, juices, and nuts, 9.5 percent of
13 red meat and 78.6 percent of fish and shellfish;
14 and

15 (5) the number of full time equivalent Food and
16 Drug Administration employees conducting inspec-
17 tions has decreased from 2003 to 2007.

18 **SEC. 602. ENSURING THE SAFETY OF PET FOOD.**

19 (a) PROCESSING AND INGREDIENT STANDARDS.—
20 Not later than 18 months after the date of enactment of
21 this Act, the Secretary of Health and Human Services (re-
22 ferred to in this title as the “Secretary”), in consultation
23 with the Association of American Feed Control Officials,
24 and other relevant stakeholder groups, including veteri-
25 nary medical associations, animal health organizations,

1 and pet food manufacturers, shall by regulation estab-
2 lish—

3 (1) processing and ingredient standards with
4 respect to pet food, animal waste, and ingredient
5 definitions; and

6 (2) updated standards for the labeling of pet
7 food that includes nutritional information and ingre-
8 dient information.

9 (b) EARLY WARNING SURVEILLANCE SYSTEMS AND
10 NOTIFICATION DURING PET FOOD RECALLS.—Not later
11 than 180 days after the date of enactment of this Act,
12 the Secretary shall by regulation establish an early warn-
13 ing and surveillance system to identify adulteration of the
14 pet food supply and outbreaks of illness associated with
15 pet food. In establishing such system, the Secretary
16 shall—

17 (1) use surveillance and monitoring mechanisms
18 similar to, or in coordination with, those mechanisms
19 used by the Centers for Disease Control and Preven-
20 tion to monitor human health, such as the
21 Foodborne Diseases Active Surveillance Network
22 (FoodNet) and PulseNet;

23 (2) consult with relevant professional associa-
24 tions and private sector veterinary hospitals; and

1 (3) work with the Health Alert Network and
2 other notification networks to inform veterinarians
3 and relevant stakeholders during any recall of pet
4 food.

5 **SEC. 603. ENSURING EFFICIENT AND EFFECTIVE COMMU-**
6 **NICATIONS DURING A RECALL.**

7 The Secretary shall, during an ongoing recall of
8 human or pet food—

9 (1) work with companies, relevant professional
10 associations, and other organizations to collect and
11 aggregate information pertaining to the recall;

12 (2) use existing networks of communication in-
13 cluding electronic forms of information dissemina-
14 tion to enhance the quality and speed of communica-
15 tion with the public; and

16 (3) post information regarding recalled prod-
17 ucts on the Internet website of the Food and Drug
18 Administration in a consolidated, searchable form
19 that is easily accessed and understood by the public.

20 **SEC. 604. STATE AND FEDERAL COOPERATION.**

21 (a) IN GENERAL.—The Secretary shall work with the
22 States in undertaking activities and programs that assist
23 in improving the safety of fresh and processed produce
24 so that State food safety programs involving the safety
25 of fresh and processed produce and activities conducted

1 by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

4 (1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

7 (2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

11 (b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

14 (1) advisory assistance;

15 (2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

18 (3) financial and other assistance.

19 (c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

1 **SEC. 605. ADULTERATED FOOD REGISTRY.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) In 1994, Congress passed the Dietary Sup-
5 plement Health and Education Act (P.L. 103–417)
6 to provide the Food and Drug Administration with
7 the legal framework to ensure that dietary supple-
8 ments are safe and properly labeled foods.

9 (2) In 2006, Congress passed the Dietary Sup-
10 plement and Nonprescription Drug Consumer Pro-
11 tection Act (P.L. 109–462) to establish a mandatory
12 reporting system of serious adverse events for non-
13 prescription drugs and dietary supplements sold and
14 consumed in the United States.

15 (3) The adverse event reporting system created
16 under the Dietary Supplement and Nonprescription
17 Drug Consumer Protection Act will serve as the
18 early warning system for any potential public health
19 issues associated with the use of these food products.

20 (4) A reliable mechanism to track patterns of
21 adulteration in food would support efforts by the
22 Food and Drug Administration to effectively target
23 limited inspection resources to protect the public
24 health.

1 (b) IN GENERAL.—Chapter IV of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
3 ed by adding at the end the following:

4 **“SEC. 417. ADULTERATED FOOD REGISTRY.**

5 “(a) DEFINITIONS.—In this section:

6 “(1) IMPORTER.—The term ‘importer’, with re-
7 spect to an article of food, means the person who
8 submitted the notice with respect to such article of
9 food under section 801(m).

10 “(2) RESPONSIBLE PARTY.—The term ‘respon-
11 sible party’, with respect to an article of food, means
12 any registered food facility under section 415(a), in-
13 cluding those responsible for the manufacturing,
14 processing, packaging or holding of such food for
15 consumption in the United States.

16 “(3) REPORTABLE ADULTERATED FOOD.—The
17 term ‘reportable adulterated food’ for purposes of
18 this section means a food that is adulterated or—

19 “(A) presents a situation in which there is
20 a reasonable probability that the use of, or ex-
21 posure to, a violative product will cause serious
22 adverse health consequences or death as defined
23 in section 7.3(m)(1) of title, Code of Federal
24 Regulations (or any successor regulations); or

1 “(B) meets the threshold established in
2 section 304(h).

3 “(b) ESTABLISHMENT.—

4 “(1) IN GENERAL.—Not later than 180 days
5 after the date of enactment of this section, the Sec-
6 retary shall establish within the Food and Drug Ad-
7 ministration an Adulterated Food Registry to which
8 instances of reportable adulterated food may be sub-
9 mitted by the Food and Drug Administration after
10 receipt of reports of adulteration, via an electronic
11 portal, from—

12 “(A) Federal, State, and local public
13 health officials;

14 “(B) an importer;

15 “(C) a responsible party; or

16 “(D) a consumer or other individual.

17 “(2) REVIEW BY SECRETARY.—The Secretary
18 shall review and determine the validity of the infor-
19 mation submitted under paragraph (1) for the pur-
20 poses of identifying adulterated food, submitting en-
21 tries to the Adulterated Food Registry, acting under
22 subsection (c), and exercising other existing food
23 safety authorities under the Act to protect the public
24 health.

25 “(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

1 “(1) IN GENERAL.—The Secretary shall issue
2 an alert with respect to an adulterated food if the
3 Adulterated Food Registry shows that the food—

4 “(A) has been associated with repeated
5 and separate outbreaks of illness or has been
6 repeatedly determined to be adulterated; or

7 “(B) is a reportable adulterated food.

8 “(2) SCOPE OF ALERT.—An alert under para-
9 graph (1) may apply to a particular food or to food
10 from a particular producer, manufacturer, shipper,
11 growing area, or country, to the extent that elements
12 in subparagraph (A) or (B) of paragraph (1) are as-
13 sociated with the particular food, producer, manu-
14 facturer, shipper, growing area, or country.

15 “(d) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a
16 report to the Food and Drug Administration using the
17 electronic portal data elements described in subsection (e).
18 Such reports shall be evaluated by the Secretary as speci-
19 fied in subsection (b)(2).

21 “(e) NOTIFICATION AND REPORTING OF ADULTERATION.—

23 “(1) DETERMINATION BY RESPONSIBLE PARTY
24 OR IMPORTER.—If a responsible party or importer
25 determines that an article of food it produced, proc-

1 essed, manufactured, distributed, or otherwise han-
2 dled is a reportable adulterated food, the responsible
3 party shall provide the notifications described under
4 paragraph (2).

5 “(2) NOTIFICATION OF ADULTERATION.—

6 “(A) IN GENERAL.—Not later than 5 days
7 after a responsible party or importer receives a
8 notification, the responsible party or importer,
9 as applicable, shall review whether the food ref-
10 erenced in the report described in paragraph
11 (1) is a reportable adulterated food.

12 “(B) NOTIFICATION.—If a determination
13 is made by such responsible party or importer
14 that the food is a reportable adulterated food,
15 such responsible party or importer shall, no
16 later than 2 days after such determination is
17 made, notify other responsible parties directly
18 linked in the supply chain to which and from
19 which the article of reportable adulterated food
20 was transferred.

21 “(3) SUBMISSION OF REPORTS TO THE FOOD
22 AND DRUG ADMINISTRATION BY A RESPONSIBLE
23 PARTY OR IMPORTER.—The responsible party or im-
24 porter, as applicable, shall submit a report to the
25 Food and Drug Administration through the elec-

1 tronic portal using the data elements described in
2 subsection (f) not later than 2 days after a respon-
3 sible party or importer—

4 “(A) makes a notification under paragraph
5 (2)(B); or

6 “(B) determines that an article of food it
7 produced, processed, manufactured, distributed,
8 imported, or otherwise handled is a reportable
9 adulterated food, except that if such adultera-
10 tion was initiated with such responsible party or
11 importer, was detected prior to any transfer of
12 such article of food, and was destroyed, no re-
13 port is necessary.

14 “(f) DATA ELEMENTS IN THE REGISTRY.—A report
15 submitted to the Food and Drug Administration electronic
16 portal under subsection (e) shall include the following data
17 elements:

18 “(1) Contact information for the individual or
19 entity submitting the report.

20 “(2) The date on which an article of food was
21 determined to be adulterated or suspected of being
22 adulterated.

23 “(3) A description of the article of food includ-
24 ing the quantity or amount.

25 “(4) The extent and nature of the adulteration.

1 “(5) The disposition of the article.

2 “(6) Product information typically found on
3 packaging including product codes, use by dates,
4 and names of manufactures or distributors.

5 “(7) Information about the place of purchase or
6 process by which the consumer or other individual
7 acquired the article of adulterated food.

8 “(8) In the case of a responsible party or an
9 importer, the elements required for the registration
10 of food facilities under section 415(a).

11 “(9) The contact information for parties di-
12 rectly linked in the supply chain and notified under
13 subsection (e)(2).

14 “(10) In the case of an importer, the elements
15 required for the prior notice of imported food ship-
16 ments under section 801(m).

17 “(g) MAINTENANCE AND INSPECTION OF
18 RECORDS.—The responsible person or importer shall
19 maintain records related to each report received, notifica-
20 tion made, and report submitted to the Food and Drug
21 Administration under this section and permit inspection
22 of such records as provided for in section 414. Such
23 records shall also be made available during an inspection
24 under section 704.

1 “(h) REQUEST FOR INFORMATION.—Section 552 of
2 title 5, United States Code, shall apply to any request for
3 information regarding a record in the Adulterated Food
4 Registry.

5 “(i) HOMELAND SECURITY NOTIFICATION.—If, after
6 receiving a report under subsection (e), the Secretary sus-
7 pects such food may have been deliberately adulterated,
8 the Secretary shall immediately notify the Secretary of
9 Homeland Security. The Secretary shall make the data in
10 the Adulterated Imported Food Registry available to the
11 Secretary of Homeland Security.”.

12 (c) DEFINITION.—Section 201(ff) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is
14 amended by striking “section 201(g)” and inserting “sec-
15 tions 201(g) and 417”.

16 (d) PROHIBITED ACTS.—Section 301 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
18 amended by this Act, is further amended by adding at the
19 end the following:

20 “(kk) The failure to provide a report as required
21 under section 417(e)(3).

22 “(ll) The falsification a report as required under sec-
23 tion 417(e)(3).”.

24 (e) SUSPECTED FOOD ADULTERATION REGULA-
25 TIONS.—The Secretary shall, within 180 days of enact-

1 ment of this Act, promulgate regulations that establish
2 standards and thresholds by which importers and respon-
3 sible parties shall be required and consumers may be able
4 to, under section 417 of the Federal Food, Drug, and Cos-
5 metic Act (as added by this section)—

6 (1) report instances of suspected reportable
7 adulteration of food to the Food and Drug Adminis-
8 tration for possible inclusion in the Adulterated
9 Food Registry after evaluation of such report; and

10 (2) notify, in keeping with subsection (e)(2) of
11 such section 417, other responsible parties directly
12 linked in the supply chain, including establishments
13 as defined in section 415(b) of such Act.

14 (f) EFFECTIVE DATE.—The requirements of section
15 417(e) of the Federal Food, Drug, and Cosmetic Act, as
16 added by subsection (a), shall become effective 180 days
17 after the date of enactment of this Act.

18 **SEC. 606. SENSE OF THE SENATE.**

19 It is the sense of the Senate that—

20 (1) it is vital for Congress to provide the Food
21 and Drug Administration with additional resources,
22 authorities, and direction with respect to ensuring
23 the safety of the food supply of the United States;

1 (2) additional inspectors are required to im-
2 prove the Food and Drug Administration's ability to
3 safeguard the food supply of the United States;

4 (3) because of the increasing volume of inter-
5 national trade in food products the Secretary of
6 Health and Human Services should make it a pri-
7 ority to enter into agreements with the trading part-
8 ners of the United States with respect to food safe-
9 ty; and

10 (4) the Senate should work to develop a com-
11 prehensive response to the issue of food safety.

12 **SEC. 607. ANNUAL REPORT TO CONGRESS.**

13 The Secretary shall, on an annual basis, submit to
14 the Committee on Health, Education, Labor, and Pen-
15 sions and the Committee on Appropriations of the Senate
16 and the Committee on Energy and Commerce and the
17 Committee on Appropriations of the House of Representa-
18 tives a report that includes, with respect to the preceding
19 1-year period—

20 (1) the number and amount of food products
21 regulated by the Food and Drug Administration im-
22 ported into the United States, aggregated by country
23 and type of food;

24 (2) a listing of the number of Food and Drug
25 Administration inspectors of imported food products

1 referenced in paragraph (1) and the number of Food
2 and Drug Administration inspections performed on
3 such products; and

4 (3) aggregated data on the findings of such in-
5 spections, including data related to violations of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 201 et seq.), and enforcement actions used to follow-
8 up on such findings and violations.

9 **SEC. 608. RULE OF CONSTRUCTION.**

10 Nothing in this title (or an amendment made by this
11 title) shall be construed to affect—

12 (1) the regulation of dietary supplements under
13 the Dietary Supplement Health and Education Act;
14 or

15 (2) the adverse event reporting system for die-
16 tary supplements created under the Dietary Supple-
17 ment and Nonprescription Drug Consumer Protec-
18 tion Act.

19 **SEC. 609. AUTHORIZATION OF APPROPRIATIONS.**

20 There are authorized to be appropriated to carry out
21 this title (and the amendments made by this title) such
22 sums as may be necessary.

1 **TITLE VII—DOMESTIC PET**
2 **TURTLE MARKET ACCESS**

3 **SEC. 701. SHORT TITLE.**

4 This title may be cited as the “Domestic Pet Turtle
5 Market Access Act of 2007”.

6 **SEC. 702. FINDINGS.**

7 Congress makes the following findings:

8 (1) Pet turtles less than 10.2 centimeters in di-
9 ameter have been banned for sale in the United
10 States by the Food and Drug Administration since
11 1975 due to health concerns.

12 (2) The Food and Drug Administration does
13 not ban the sale of iguanas or other lizards, snakes,
14 frogs, or other amphibians or reptiles that are sold
15 as pets in the United States that also carry sal-
16 monella bacteria. The Food and Drug Administra-
17 tion also does not require that these animals be
18 treated for salmonella bacteria before being sold as
19 pets.

20 (3) The technology to treat turtles for sal-
21 monella, and make them safe for sale, has greatly
22 advanced since 1975. Treatments exist that can
23 nearly eradicate salmonella from turtles, and individ-
24 uals are more aware of the causes of salmonella, how

1 to treat salmonella poisoning, and the seriousness
2 associated with salmonella poisoning.

3 (4) University research has shown that these
4 turtles can be treated in such a way that they can
5 be raised, shipped, and distributed without having a
6 recolonization of salmonella.

7 (5) University research has also shown that pet
8 owners can be equipped with a treatment regiment
9 that allows the turtle to be maintained safe from sal-
10 monella.

11 (6) The Food and Drug Administration should
12 allow the sale of turtles less than 10.2 centimeters
13 in diameter as pets as long as the sellers are re-
14 quired to use proven methods to treat these turtles
15 for salmonella.

16 **SEC. 703. SALE OF BABY TURTLES.**

17 Notwithstanding any other provision of law, the Food
18 and Drug Administration shall not restrict the sale by a
19 turtle farmer, wholesaler, or commercial retail seller of a
20 turtle that is less than 10.2 centimeters in diameter as
21 a pet if—

22 (1) the State or territory in which such farmer
23 is located has developed a regulatory process by
24 which pet turtle farmers are required to have a
25 State license to breed, hatch, propagate, raise, grow,

1 receive, ship, transport, export, or sell pet turtles or
2 pet turtle eggs;

3 (2) such State or territory requires certification
4 of sanitization that is signed by a veterinarian who
5 is licensed in the State or territory, and approved by
6 the State or territory agency in charge of regulating
7 the sale of pet turtles;

8 (3) the certification of sanitization requires
9 each turtle to be sanitized or treated for diseases, in-
10 cluding salmonella, and is dependant upon using the
11 Siebeling method, or other such proven non-anti-
12 biotic method, to make the turtle salmonella-free;
13 and

14 (4) the turtle farmer or commercial retail seller
15 includes, with the sale of such a turtle, a disclosure
16 to the buyer that includes—

17 (A) information regarding—

18 (i) the possibility that salmonella can
19 re-colonize in turtles;

20 (ii) the dangers, including possible se-
21 vere illness or death, especially for at-risk
22 people who may be susceptible to sal-
23 monella poisoning, such as children, preg-
24 nant women, and others who may have
25 weak immune systems, that could result if

1 the turtle is not properly handled and safe-
2 ly maintained;

3 (iii) the proper handling of the turtle,
4 including an explanation of proper hygiene
5 such as handwashing after handling a tur-
6 tle; and

7 (iv) the proven methods of treatment
8 that, if properly applied, keep the turtle
9 safe from salmonella;

10 (B) a detailed explanation of how to prop-
11 erly treat the turtle to keep it safe from sal-
12 monella, using the proven methods of treatment
13 referred to under subparagraph (A), and how
14 the buyer can continue to purchase the tools,
15 treatments, or any other required item to con-
16 tinually treat the turtle; and

17 (C) a statement that buyers of pet turtles
18 should not abandon the turtle or abandon it
19 outside, as the turtle may become an invasive
20 species to the local community, but should in-
21 stead return them to a commercial retail pet
22 seller or other organization that would accept
23 turtles no longer wanted as pets.

1 **SEC. 704. FDA REVIEW OF STATE PROTECTIONS.**

2 The Commissioner of Food and Drugs may, after
3 providing an opportunity for the affected State to respond,
4 restrict the sale of a turtle only if the Secretary of Health
5 and Human Services determines that the actual implemen-
6 tation of State health protections described in this title
7 are insufficient to protect consumers against infectious
8 diseases acquired from such turtle at the time of sale.

9 **TITLE VIII—IMPORTATION OF**
10 **PRESCRIPTION DRUGS**

11 **SEC. 801. SHORT TITLE.**

12 This title may be cited as the “Pharmaceutical Mar-
13 ket Access and Drug Safety Act of 2007”.

14 **SEC. 802. FINDINGS.**

15 Congress finds that—

16 (1) Americans unjustly pay up to 5 times more
17 to fill their prescriptions than consumers in other
18 countries;

19 (2) the United States is the largest market for
20 pharmaceuticals in the world, yet American con-
21 sumers pay the highest prices for brand pharma-
22 ceuticals in the world;

23 (3) a prescription drug is neither safe nor effec-
24 tive to an individual who cannot afford it;

25 (4) allowing and structuring the importation of
26 prescription drugs to ensure access to safe and af-

1 fordable drugs approved by the Food and Drug Ad-
 2 ministration will provide a level of safety to Amer-
 3 ican consumers that they do not currently enjoy;

4 (5) American spend more than
 5 \$200,000,000,000 on prescription drugs every year;

6 (6) the Congressional Budget Office has found
 7 that the cost of prescription drugs are between 35
 8 to 55 percent less in other highly-developed coun-
 9 tries than in the United States; and

10 (7) promoting competitive market pricing would
 11 both contribute to health care savings and allow
 12 greater access to therapy, improving health and sav-
 13 ing lives.

14 **SEC. 803. REPEAL OF CERTAIN SECTION REGARDING IM-**
 15 **PORTATION OF PRESCRIPTION DRUGS.**

16 Chapter VIII of the Federal Food, Drug, and Cos-
 17 metic Act (21 U.S.C. 381 et seq.) is amended by striking
 18 section 804.

19 **SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
 20 **OF CERTAIN IMPORT RESTRICTIONS.**

21 (a) IN GENERAL.—Chapter VIII of the Federal
 22 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
 23 as amended by section 803, is further amended by insert-
 24 ing after section 803 the following:

1 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
2 **PRESCRIPTION DRUGS.**

3 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

4 “(1) IN GENERAL.—In the case of qualifying
5 drugs imported or offered for import into the United
6 States from registered exporters or by registered im-
7 porters—

8 “(A) the limitation on importation that is
9 established in section 801(d)(1) is waived; and

10 “(B) the standards referred to in section
11 801(a) regarding admission of the drugs are
12 subject to subsection (g) of this section (includ-
13 ing with respect to qualifying drugs to which
14 section 801(d)(1) does not apply).

15 “(2) IMPORTERS.—A qualifying drug may not
16 be imported under paragraph (1) unless—

17 “(A) the drug is imported by a pharmacy,
18 group of pharmacies, or a wholesaler that is a
19 registered importer; or

20 “(B) the drug is imported by an individual
21 for personal use or for the use of a family mem-
22 ber of the individual (not for resale) from a reg-
23 istered exporter.

24 “(3) RULE OF CONSTRUCTION.—This section
25 shall apply only with respect to a drug that is im-

1 ported or offered for import into the United
2 States—

3 “(A) by a registered importer; or

4 “(B) from a registered exporter to an indi-
5 vidual.

6 “(4) DEFINITIONS.—

7 “(A) REGISTERED EXPORTER; REG-
8 ISTERED IMPORTER.—For purposes of this sec-
9 tion:

10 “(i) The term ‘registered exporter’
11 means an exporter for which a registration
12 under subsection (b) has been approved
13 and is in effect.

14 “(ii) The term ‘registered importer’
15 means a pharmacy, group of pharmacies,
16 or a wholesaler for which a registration
17 under subsection (b) has been approved
18 and is in effect.

19 “(iii) The term ‘registration condition’
20 means a condition that must exist for a
21 registration under subsection (b) to be ap-
22 proved.

23 “(B) QUALIFYING DRUG.—For purposes of
24 this section, the term ‘qualifying drug’ means a

1 drug for which there is a corresponding U.S.
2 label drug.

3 “(C) U.S. LABEL DRUG.—For purposes of
4 this section, the term ‘U.S. label drug’ means
5 a prescription drug that—

6 “(i) with respect to a qualifying drug,
7 has the same active ingredient or ingredi-
8 ents, route of administration, dosage form,
9 and strength as the qualifying drug;

10 “(ii) with respect to the qualifying
11 drug, is manufactured by or for the person
12 that manufactures the qualifying drug;

13 “(iii) is approved under section
14 505(c); and

15 “(iv) is not—

16 “(I) a controlled substance, as
17 defined in section 102 of the Con-
18 trolled Substances Act (21 U.S.C.
19 802);

20 “(II) a biological product, as de-
21 fined in section 351 of the Public
22 Health Service Act (42 U.S.C. 262),
23 including—

24 “(aa) a therapeutic DNA
25 plasmid product;

1 “(bb) a therapeutic synthetic
2 peptide product;

3 “(cc) a monoclonal antibody
4 product for in vivo use; and

5 “(dd) a therapeutic recom-
6 binant DNA-derived product;

7 “(III) an infused drug, including
8 a peritoneal dialysis solution;

9 “(IV) an injected drug;

10 “(V) a drug that is inhaled dur-
11 ing surgery;

12 “(VI) a drug that is the listed
13 drug referred to in 2 or more abbrevi-
14 ated new drug applications under
15 which the drug is commercially mar-
16 keted; or

17 “(VII) a sterile ophthalmic drug
18 intended for topical use on or in the
19 eye.

20 “(D) OTHER DEFINITIONS.—For purposes
21 of this section:

22 “(i)(I) The term ‘exporter’ means a
23 person that is in the business of exporting
24 a drug to individuals in the United States
25 from Canada or from a permitted country

1 designated by the Secretary under sub-
2 clause (II), or that, pursuant to submitting
3 a registration under subsection (b), seeks
4 to be in such business.

5 “(II) The Secretary shall designate a
6 permitted country under subparagraph (E)
7 (other than Canada) as a country from
8 which an exporter may export a drug to in-
9 dividuals in the United States if the Sec-
10 retary determines that—

11 “(aa) the country has statutory
12 or regulatory standards that are
13 equivalent to the standards in the
14 United States and Canada with re-
15 spect to—

16 “(AA) the training of phar-
17 macists;

18 “(BB) the practice of phar-
19 macy; and

20 “(CC) the protection of the
21 privacy of personal medical infor-
22 mation; and

23 “(bb) the importation of drugs to
24 individuals in the United States from

1 the country will not adversely affect
2 public health.

3 “(ii) The term ‘importer’ means a
4 pharmacy, a group of pharmacies, or a
5 wholesaler that is in the business of im-
6 porting a drug into the United States or
7 that, pursuant to submitting a registration
8 under subsection (b), seeks to be in such
9 business.

10 “(iii) The term ‘pharmacist’ means a
11 person licensed by a State to practice
12 pharmacy, including the dispensing and
13 selling of prescription drugs.

14 “(iv) The term ‘pharmacy’ means a
15 person that—

16 “(I) is licensed by a State to en-
17 gage in the business of selling pre-
18 scription drugs at retail; and

19 “(II) employs 1 or more phar-
20 macists.

21 “(v) The term ‘prescription drug’
22 means a drug that is described in section
23 503(b)(1).

24 “(vi) The term ‘wholesaler’—

1 “(I) means a person licensed as a
2 wholesaler or distributor of prescrip-
3 tion drugs in the United States under
4 section 503(e)(2)(A); and

5 “(II) does not include a person
6 authorized to import drugs under sec-
7 tion 801(d)(1).

8 “(E) PERMITTED COUNTRY.—The term
9 ‘permitted country’ means—

10 “(i) Australia;

11 “(ii) Canada;

12 “(iii) a member country of the Euro-
13 pean Union, but does not include a mem-
14 ber country with respect to which—

15 “(I) the country’s Annex to the
16 Treaty of Accession to the European
17 Union 2003 includes a transitional
18 measure for the regulation of human
19 pharmaceutical products that has not
20 expired; or

21 “(II) the Secretary determines
22 that the requirements described in
23 subclauses (I) and (II) of clause (vii)
24 will not be met by the date on which
25 such transitional measure for the reg-

1 ulation of human pharmaceutical
2 products expires;
3 “(iv) Japan;
4 “(v) New Zealand;
5 “(vi) Switzerland; and
6 “(vii) a country in which the Sec-
7 retary determines the following require-
8 ments are met:

9 “(I) The country has statutory or
10 regulatory requirements—

11 “(aa) that require the review
12 of drugs for safety and effective-
13 ness by an entity of the govern-
14 ment of the country;

15 “(bb) that authorize the ap-
16 proval of only those drugs that
17 have been determined to be safe
18 and effective by experts employed
19 by or acting on behalf of such en-
20 tity and qualified by scientific
21 training and experience to evalu-
22 ate the safety and effectiveness of
23 drugs on the basis of adequate
24 and well-controlled investigations,
25 including clinical investigations,

1 conducted by experts qualified by
2 scientific training and experience
3 to evaluate the safety and effec-
4 tiveness of drugs;

5 “(cc) that require the meth-
6 ods used in, and the facilities and
7 controls used for the manufac-
8 ture, processing, and packing of
9 drugs in the country to be ade-
10 quate to preserve their identity,
11 quality, purity, and strength;

12 “(dd) for the reporting of
13 adverse reactions to drugs and
14 procedures to withdraw approval
15 and remove drugs found not to
16 be safe or effective; and

17 “(ee) that require the label-
18 ing and promotion of drugs to be
19 in accordance with the approval
20 of the drug.

21 “(II) The valid marketing au-
22 thorization system in the country is
23 equivalent to the systems in the coun-
24 tries described in clauses (i) through
25 (vi).

1 “(III) The importation of drugs
2 to the United States from the country
3 will not adversely affect public health.

4 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
5 ERS.—

6 “(1) REGISTRATION OF IMPORTERS AND EX-
7 PORTERS.—A registration condition is that the im-
8 porter or exporter involved (referred to in this sub-
9 section as a ‘registrant’) submits to the Secretary a
10 registration containing the following:

11 “(A)(i) In the case of an exporter, the
12 name of the exporter and an identification of all
13 places of business of the exporter that relate to
14 qualifying drugs, including each warehouse or
15 other facility owned or controlled by, or oper-
16 ated for, the exporter.

17 “(ii) In the case of an importer, the name
18 of the importer and an identification of the
19 places of business of the importer at which the
20 importer initially receives a qualifying drug
21 after importation (which shall not exceed 3
22 places of business except by permission of the
23 Secretary).

24 “(B) Such information as the Secretary
25 determines to be necessary to demonstrate that

1 the registrant is in compliance with registration
2 conditions under—

3 “(i) in the case of an importer, sub-
4 sections (c), (d), (e), (g), and (j) (relating
5 to the sources of imported qualifying
6 drugs; the inspection of facilities of the im-
7 porter; the payment of fees; compliance
8 with the standards referred to in section
9 801(a); and maintenance of records and
10 samples); or

11 “(ii) in the case of an exporter, sub-
12 sections (c), (d), (f), (g), (h), (i), and (j)
13 (relating to the sources of exported quali-
14 fying drugs; the inspection of facilities of
15 the exporter and the marking of compliant
16 shipments; the payment of fees; and com-
17 pliance with the standards referred to in
18 section 801(a); being licensed as a phar-
19 macist; conditions for individual importa-
20 tion; and maintenance of records and sam-
21 ples).

22 “(C) An agreement by the registrant that
23 the registrant will not under subsection (a) im-
24 port or export any drug that is not a qualifying
25 drug.

1 “(D) An agreement by the registrant to—

2 “(i) notify the Secretary of a recall or
3 withdrawal of a qualifying drug distributed
4 in a permitted country that the registrant
5 has exported or imported, or intends to ex-
6 port or import, to the United States under
7 subsection (a);

8 “(ii) provide for the return to the reg-
9 istrant of such drug; and

10 “(iii) cease, or not begin, the expor-
11 tation or importation of such drug unless
12 the Secretary has notified the registrant
13 that exportation or importation of such
14 drug may proceed.

15 “(E) An agreement by the registrant to
16 ensure and monitor compliance with each reg-
17 istration condition, to promptly correct any
18 noncompliance with such a condition, and to
19 promptly report to the Secretary any such non-
20 compliance.

21 “(F) A plan describing the manner in
22 which the registrant will comply with the agree-
23 ment under subparagraph (E).

24 “(G) An agreement by the registrant to
25 enforce a contract under subsection (c)(3)(B)

1 against a party in the chain of custody of a
2 qualifying drug with respect to the authority of
3 the Secretary under clauses (ii) and (iii) of that
4 subsection.

5 “(H) An agreement by the registrant to
6 notify the Secretary not more than 30 days be-
7 fore the registrant intends to make the change,
8 of—

9 “(i) any change that the registrant in-
10 tends to make regarding information pro-
11 vided under subparagraph (A) or (B); and

12 “(ii) any change that the registrant
13 intends to make in the compliance plan
14 under subparagraph (F).

15 “(I) In the case of an exporter—

16 “(i) An agreement by the exporter
17 that a qualifying drug will not under sub-
18 section (a) be exported to any individual
19 not authorized pursuant to subsection
20 (a)(2)(B) to be an importer of such drug.

21 “(ii) An agreement to post a bond,
22 payable to the Treasury of the United
23 States that is equal in value to the lesser
24 of—

1 “(I) the value of drugs exported
2 by the exporter to the United States
3 in a typical 4-week period over the
4 course of a year under this section; or

5 “(II) \$1,000,000;

6 “(iii) An agreement by the exporter to
7 comply with applicable provisions of Cana-
8 dian law, or the law of the permitted coun-
9 try designated under subsection
10 (a)(4)(D)(i)(II) in which the exporter is lo-
11 cated, that protect the privacy of personal
12 information with respect to each individual
13 importing a prescription drug from the ex-
14 porter under subsection (a)(2)(B).

15 “(iv) An agreement by the exporter to
16 report to the Secretary—

17 “(I) not later than August 1 of
18 each fiscal year, the total price and
19 the total volume of drugs exported to
20 the United States by the exporter dur-
21 ing the 6-month period from January
22 1 through June 30 of that year; and

23 “(II) not later than January 1 of
24 each fiscal year, the total price and
25 the total volume of drugs exported to

1 the United States by the exporter dur-
2 ing the previous fiscal year.

3 “(J) In the case of an importer, an agree-
4 ment by the importer to report to the Sec-
5 retary—

6 “(i) not later than August 1 of each
7 fiscal year, the total price and the total
8 volume of drugs imported to the United
9 States by the importer during the 6-month
10 period from January 1 through June 30 of
11 that fiscal year; and

12 “(ii) not later than January 1 of each
13 fiscal year, the total price and the total
14 volume of drugs imported to the United
15 States by the importer during the previous
16 fiscal year.

17 “(K) Such other provisions as the Sec-
18 retary may require by regulation to protect the
19 public health while permitting—

20 “(i) the importation by pharmacies,
21 groups of pharmacies, and wholesalers as
22 registered importers of qualifying drugs
23 under subsection (a); and

24 “(ii) importation by individuals of
25 qualifying drugs under subsection (a).

1 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
2 TION.—

3 “(A) IN GENERAL.—Not later than 90
4 days after the date on which a registrant sub-
5 mits to the Secretary a registration under para-
6 graph (1), the Secretary shall notify the reg-
7 istrant whether the registration is approved or
8 is disapproved. The Secretary shall disapprove
9 a registration if there is reason to believe that
10 the registrant is not in compliance with one or
11 more registration conditions, and shall notify
12 the registrant of such reason. In the case of a
13 disapproved registration, the Secretary shall
14 subsequently notify the registrant that the reg-
15 istration is approved if the Secretary deter-
16 mines that the registrant is in compliance with
17 such conditions.

18 “(B) CHANGES IN REGISTRATION INFOR-
19 MATION.—Not later than 30 days after receiv-
20 ing a notice under paragraph (1)(H) from a
21 registrant, the Secretary shall determine wheth-
22 er the change involved affects the approval of
23 the registration of the registrant under para-
24 graph (1), and shall inform the registrant of
25 the determination.

1 “(3) PUBLICATION OF CONTACT INFORMATION
2 FOR REGISTERED EXPORTERS.—Through the Inter-
3 net website of the Food and Drug Administration
4 and a toll-free telephone number, the Secretary shall
5 make readily available to the public a list of reg-
6 istered exporters, including contact information for
7 the exporters. Promptly after the approval of a reg-
8 istration submitted under paragraph (1), the Sec-
9 retary shall update the Internet website and the in-
10 formation provided through the toll-free telephone
11 number accordingly.

12 “(4) SUSPENSION AND TERMINATION.—

13 “(A) SUSPENSION.—With respect to the
14 effectiveness of a registration submitted under
15 paragraph (1):

16 “(i) Subject to clause (ii), the Sec-
17 retary may suspend the registration if the
18 Secretary determines, after notice and op-
19 portunity for a hearing, that the registrant
20 has failed to maintain substantial compli-
21 ance with a registration condition.

22 “(ii) If the Secretary determines that,
23 under color of the registration, the ex-
24 porter has exported a drug or the importer
25 has imported a drug that is not a quali-

1 fying drug, or a drug that does not comply
2 with subsection (g)(2)(A) or (g)(4), or has
3 exported a qualifying drug to an individual
4 in violation of subsection (i)(2)(F), the
5 Secretary shall immediately suspend the
6 registration. A suspension under the pre-
7 ceding sentence is not subject to the provi-
8 sion by the Secretary of prior notice, and
9 the Secretary shall provide to the reg-
10 istrant an opportunity for a hearing not
11 later than 10 days after the date on which
12 the registration is suspended.

13 “(iii) The Secretary may reinstate the
14 registration, whether suspended under
15 clause (i) or (ii), if the Secretary deter-
16 mines that the registrant has demonstrated
17 that further violations of registration con-
18 ditions will not occur.

19 “(B) TERMINATION.—The Secretary, after
20 notice and opportunity for a hearing, may ter-
21 minate the registration under paragraph (1) of
22 a registrant if the Secretary determines that
23 the registrant has engaged in a pattern or prac-
24 tice of violating 1 or more registration condi-
25 tions, or if on 1 or more occasions the Secretary

1 has under subparagraph (A)(ii) suspended the
2 registration of the registrant. The Secretary
3 may make the termination permanent, or for a
4 fixed period of not less than 1 year. During the
5 period in which the registration is terminated,
6 any registration submitted under paragraph (1)
7 by the registrant, or a person that is a partner
8 in the export or import enterprise, or a prin-
9 cipal officer in such enterprise, and any reg-
10 istration prepared with the assistance of the
11 registrant or such a person, has no legal effect
12 under this section.

13 “(5) DEFAULT OF BOND.—A bond required to
14 be posted by an exporter under paragraph (1)(I)(ii)
15 shall be defaulted and paid to the Treasury of the
16 United States if, after opportunity for an informal
17 hearing, the Secretary determines that the exporter
18 has—

19 “(A) exported a drug to the United States
20 that is not a qualifying drug or that is not in
21 compliance with subsection (g)(2)(A), (g)(4), or
22 (i); or

23 “(B) failed to permit the Secretary to con-
24 duct an inspection described under subsection
25 (d).

1 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
2 tion condition is that the exporter or importer involved
3 agrees that a qualifying drug will under subsection (a) be
4 exported or imported into the United States only if there
5 is compliance with the following:

6 “(1) The drug was manufactured in an estab-
7 lishment—

8 “(A) required to register under subsection
9 (h) or (i) of section 510; and

10 “(B)(i) inspected by the Secretary; or

11 “(ii) for which the Secretary has elected to
12 rely on a satisfactory report of a good manufac-
13 turing practice inspection of the establishment
14 from a permitted country whose regulatory sys-
15 tem the Secretary recognizes as equivalent
16 under a mutual recognition agreement, as pro-
17 vided for under section 510(i)(3), section 803,
18 or part 26 of title 21, Code of Federal Regula-
19 tions (or any corresponding successor rule or
20 regulation).

21 “(2) The establishment is located in any coun-
22 try, and the establishment manufactured the drug
23 for distribution in the United States or for distribu-
24 tion in 1 or more of the permitted countries (without
25 regard to whether in addition the drug is manufac-

1 tured for distribution in a foreign country that is
2 not a permitted country).

3 “(3) The exporter or importer obtained the
4 drug—

5 “(A) directly from the establishment; or

6 “(B) directly from an entity that, by con-
7 tract with the exporter or importer—

8 “(i) provides to the exporter or im-
9 porter a statement (in such form and con-
10 taining such information as the Secretary
11 may require) that, for the chain of custody
12 from the establishment, identifies each
13 prior sale, purchase, or trade of the drug
14 (including the date of the transaction and
15 the names and addresses of all parties to
16 the transaction);

17 “(ii) agrees to permit the Secretary to
18 inspect such statements and related
19 records to determine their accuracy;

20 “(iii) agrees, with respect to the quali-
21 fying drugs involved, to permit the Sec-
22 retary to inspect warehouses and other fa-
23 cilities, including records, of the entity for
24 purposes of determining whether the facili-
25 ties are in compliance with any standards

1 under this Act that are applicable to facili-
2 ties of that type in the United States; and

3 “(iv) has ensured, through such con-
4 tractual relationships as may be necessary,
5 that the Secretary has the same authority
6 regarding other parties in the chain of cus-
7 tody from the establishment that the Sec-
8 retary has under clauses (ii) and (iii) re-
9 garding such entity.

10 “(4)(A) The foreign country from which the im-
11 porter will import the drug is a permitted country;
12 or

13 “(B) The foreign country from which the ex-
14 porter will export the drug is the permitted country
15 in which the exporter is located.

16 “(5) During any period in which the drug was
17 not in the control of the manufacturer of the drug,
18 the drug did not enter any country that is not a per-
19 mitted country.

20 “(6) The exporter or importer retains a sample
21 of each lot of the drug for testing by the Secretary.

22 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
23 MENTS.—

24 “(1) INSPECTION OF FACILITIES.—A registra-
25 tion condition is that, for the purpose of assisting

1 the Secretary in determining whether the exporter
2 involved is in compliance with all other registration
3 conditions—

4 “(A) the exporter agrees to permit the Sec-
5 retary—

6 “(i) to conduct onsite inspections, in-
7 cluding monitoring on a day-to-day basis,
8 of places of business of the exporter that
9 relate to qualifying drugs, including each
10 warehouse or other facility owned or con-
11 trolled by, or operated for, the exporter;

12 “(ii) to have access, including on a
13 day-to-day basis, to—

14 “(I) records of the exporter that
15 relate to the export of such drugs, in-
16 cluding financial records; and

17 “(II) samples of such drugs;

18 “(iii) to carry out the duties described
19 in paragraph (3); and

20 “(iv) to carry out any other functions
21 determined by the Secretary to be nec-
22 essary regarding the compliance of the ex-
23 porter; and

24 “(B) the Secretary has assigned 1 or more
25 employees of the Secretary to carry out the

1 functions described in this subsection for the
2 Secretary randomly, but not less than 12 times
3 annually, on the premises of places of busi-
4 nesses referred to in subparagraph (A)(i), and
5 such an assignment remains in effect on a con-
6 tinuous basis.

7 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
8 registration condition is that the exporter involved
9 agrees to affix to each shipping container of quali-
10 fying drugs exported under subsection (a) such
11 markings as the Secretary determines to be nec-
12 essary to identify the shipment as being in compli-
13 ance with all registration conditions. Markings under
14 the preceding sentence shall—

15 “(A) be designed to prevent affixation of
16 the markings to any shipping container that is
17 not authorized to bear the markings; and

18 “(B) include anticounterfeiting or track-
19 and-trace technologies, taking into account the
20 economic and technical feasibility of those tech-
21 nologies.

22 “(3) CERTAIN DUTIES RELATING TO EXPORT-
23 ERS.—Duties of the Secretary with respect to an ex-
24 porter include the following:

1 “(A) Inspecting, randomly, but not less
2 than 12 times annually, the places of business
3 of the exporter at which qualifying drugs are
4 stored and from which qualifying drugs are
5 shipped.

6 “(B) During the inspections under sub-
7 paragraph (A), verifying the chain of custody of
8 a statistically significant sample of qualifying
9 drugs from the establishment in which the drug
10 was manufactured to the exporter, which shall
11 be accomplished or supplemented by the use of
12 anticounterfeiting or track-and-trace tech-
13 nologies, taking into account the economic and
14 technical feasibility of those technologies, except
15 that a drug that lacks such technologies from
16 the point of manufacture shall not for that rea-
17 son be excluded from importation by an ex-
18 porter.

19 “(C) Randomly reviewing records of ex-
20 ports to individuals for the purpose of deter-
21 mining whether the drugs are being imported
22 by the individuals in accordance with the condi-
23 tions under subsection (i). Such reviews shall be
24 conducted in a manner that will result in a sta-

1 tistically significant determination of compli-
2 ance with all such conditions.

3 “(D) Monitoring the affixing of markings
4 under paragraph (2).

5 “(E) Inspecting as the Secretary deter-
6 mines is necessary the warehouses and other fa-
7 cilities, including records, of other parties in the
8 chain of custody of qualifying drugs.

9 “(F) Determining whether the exporter is
10 in compliance with all other registration condi-
11 tions.

12 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-
13 istration condition is that, not less than 8 hours and
14 not more than 5 days in advance of the time of the
15 importation of a shipment of qualifying drugs, the
16 importer involved agrees to submit to the Secretary
17 a notice with respect to the shipment of drugs to be
18 imported or offered for import into the United
19 States under subsection (a). A notice under the pre-
20 ceding sentence shall include—

21 “(A) the name and complete contact infor-
22 mation of the person submitting the notice;

23 “(B) the name and complete contact infor-
24 mation of the importer involved;

1 “(C) the identity of the drug, including the
2 established name of the drug, the quantity of
3 the drug, and the lot number assigned by the
4 manufacturer;

5 “(D) the identity of the manufacturer of
6 the drug, including the identity of the establish-
7 ment at which the drug was manufactured;

8 “(E) the country from which the drug is
9 shipped;

10 “(F) the name and complete contact infor-
11 mation for the shipper of the drug;

12 “(G) anticipated arrival information, in-
13 cluding the port of arrival and crossing location
14 within that port, and the date and time;

15 “(H) a summary of the chain of custody of
16 the drug from the establishment in which the
17 drug was manufactured to the importer;

18 “(I) a declaration as to whether the Sec-
19 retary has ordered that importation of the drug
20 from the permitted country cease under sub-
21 section (g)(2)(C) or (D); and

22 “(J) such other information as the Sec-
23 retary may require by regulation.

24 “(5) MARKING OF COMPLIANT SHIPMENTS.—A
25 registration condition is that the importer involved

1 agrees, before wholesale distribution (as defined in
2 section 503(e)) of a qualifying drug that has been
3 imported under subsection (a), to affix to each con-
4 tainer of such drug such markings or other tech-
5 nology as the Secretary determines necessary to
6 identify the shipment as being in compliance with all
7 registration conditions, except that the markings or
8 other technology shall not be required on a drug
9 that bears comparable, compatible markings or tech-
10 nology from the manufacturer of the drug. Markings
11 or other technology under the preceding sentence
12 shall—

13 “(A) be designed to prevent affixation of
14 the markings or other technology to any con-
15 tainer that is not authorized to bear the mark-
16 ings; and

17 “(B) shall include anticounterfeiting or
18 track-and-trace technologies, taking into ac-
19 count the economic and technical feasibility of
20 such technologies.

21 “(6) CERTAIN DUTIES RELATING TO IMPORT-
22 ERS.—Duties of the Secretary with respect to an im-
23 porter include the following:

24 “(A) Inspecting, randomly, but not less
25 than 12 times annually, the places of business

1 of the importer at which a qualifying drug is
2 initially received after importation.

3 “(B) During the inspections under sub-
4 paragraph (A), verifying the chain of custody of
5 a statistically significant sample of qualifying
6 drugs from the establishment in which the drug
7 was manufactured to the importer, which shall
8 be accomplished or supplemented by the use of
9 anticounterfeiting or track-and-trace tech-
10 nologies, taking into account the economic and
11 technical feasibility of those technologies, except
12 that a drug that lacks such technologies from
13 the point of manufacture shall not for that rea-
14 son be excluded from importation by an im-
15 porter.

16 “(C) Reviewing notices under paragraph
17 (4).

18 “(D) Inspecting as the Secretary deter-
19 mines is necessary the warehouses and other fa-
20 cilities, including records of other parties in the
21 chain of custody of qualifying drugs.

22 “(E) Determining whether the importer is
23 in compliance with all other registration condi-
24 tions.

25 “(e) IMPORTER FEES.—

1 “(1) REGISTRATION FEE.—A registration con-
2 dition is that the importer involved pays to the Sec-
3 retary a fee of \$10,000 due on the date on which
4 the importer first submits the registration to the
5 Secretary under subsection (b).

6 “(2) INSPECTION FEE.—A registration condi-
7 tion is that the importer involved pays a fee to the
8 Secretary in accordance with this subsection. Such
9 fee shall be paid not later than October 1 and April
10 1 of each fiscal year in the amount provided for
11 under paragraph (3).

12 “(3) AMOUNT OF INSPECTION FEE.—

13 “(A) AGGREGATE TOTAL OF FEES.—Not
14 later than 30 days before the start of each fis-
15 cal year, the Secretary, in consultation with the
16 Secretary of Homeland Security and the Sec-
17 retary of the Treasury, shall establish an aggre-
18 gate total of fees to be collected under para-
19 graph (2) for importers for that fiscal year that
20 is sufficient, and not more than necessary, to
21 pay the costs for that fiscal year of admin-
22 istering this section with respect to registered
23 importers, including the costs associated with—

24 “(i) inspecting the facilities of reg-
25 istered importers, and of other entities in

1 the chain of custody of a qualifying drug
2 as necessary, under subsection (d)(6);

3 “(ii) developing, implementing, and
4 operating under such subsection an elec-
5 tronic system for submission and review of
6 the notices required under subsection
7 (d)(4) with respect to shipments of quali-
8 fying drugs under subsection (a) to assess
9 compliance with all registration conditions
10 when such shipments are offered for im-
11 port into the United States; and

12 “(iii) inspecting such shipments as
13 necessary, when offered for import into the
14 United States to determine if such a ship-
15 ment should be refused admission under
16 subsection (g)(5).

17 “(B) LIMITATION.—Subject to subpara-
18 graph (C), the aggregate total of fees collected
19 under paragraph (2) for a fiscal year shall not
20 exceed 2.5 percent of the total price of quali-
21 fying drugs imported during that fiscal year
22 into the United States by registered importers
23 under subsection (a).

24 “(C) TOTAL PRICE OF DRUGS.—

1 “(i) ESTIMATE.—For the purposes of
2 complying with the limitation described in
3 subparagraph (B) when establishing under
4 subparagraph (A) the aggregate total of
5 fees to be collected under paragraph (2)
6 for a fiscal year, the Secretary shall esti-
7 mate the total price of qualifying drugs im-
8 ported into the United States by registered
9 importers during that fiscal year by adding
10 the total price of qualifying drugs imported
11 by each registered importer during the 6-
12 month period from January 1 through
13 June 30 of the previous fiscal year, as re-
14 ported to the Secretary by each registered
15 importer under subsection (b)(1)(J).

16 “(ii) CALCULATION.—Not later than
17 March 1 of the fiscal year that follows the
18 fiscal year for which the estimate under
19 clause (i) is made, the Secretary shall cal-
20 culate the total price of qualifying drugs
21 imported into the United States by reg-
22 istered importers during that fiscal year by
23 adding the total price of qualifying drugs
24 imported by each registered importer dur-
25 ing that fiscal year, as reported to the Sec-

1 retary by each registered importer under
2 subsection (b)(1)(J).

3 “(iii) ADJUSTMENT.—If the total
4 price of qualifying drugs imported into the
5 United States by registered importers dur-
6 ing a fiscal year as calculated under clause
7 (ii) is less than the aggregate total of fees
8 collected under paragraph (2) for that fis-
9 cal year, the Secretary shall provide for a
10 pro-rata reduction in the fee due from each
11 registered importer on April 1 of the sub-
12 sequent fiscal year so that the limitation
13 described in subparagraph (B) is observed.

14 “(D) INDIVIDUAL IMPORTER FEE.—Sub-
15 ject to the limitation described in subparagraph
16 (B), the fee under paragraph (2) to be paid on
17 October 1 and April 1 by an importer shall be
18 an amount that is proportional to a reasonable
19 estimate by the Secretary of the semiannual
20 share of the importer of the volume of quali-
21 fying drugs imported by importers under sub-
22 section (a).

23 “(4) USE OF FEES.—

24 “(A) IN GENERAL.—Subject to appropria-
25 tions Acts, fees collected by the Secretary under

1 paragraphs (1) and (2) shall be credited to the
2 appropriation account for salaries and expenses
3 of the Food and Drug Administration until ex-
4 pended (without fiscal year limitation), and the
5 Secretary may, in consultation with the Sec-
6 retary of Homeland Security and the Secretary
7 of the Treasury, transfer some proportion of
8 such fees to the appropriation account for sala-
9 ries and expenses of the Bureau of Customs
10 and Border Protection until expended (without
11 fiscal year limitation).

12 “(B) SOLE PURPOSE.—Fees collected by
13 the Secretary under paragraphs (1) and (2) are
14 only available to the Secretary and, if trans-
15 ferred, to the Secretary of Homeland Security,
16 and are for the sole purpose of paying the costs
17 referred to in paragraph (3)(A).

18 “(5) COLLECTION OF FEES.—In any case where
19 the Secretary does not receive payment of a fee as-
20 sessed under paragraph (1) or (2) within 30 days
21 after it is due, such fee shall be treated as a claim
22 of the United States Government subject to sub-
23 chapter II of chapter 37 of title 31, United States
24 Code.

25 “(f) EXPORTER FEES.—

1 “(1) REGISTRATION FEE.—A registration con-
2 dition is that the exporter involved pays to the Sec-
3 retary a fee of \$10,000 due on the date on which
4 the exporter first submits that registration to the
5 Secretary under subsection (b).

6 “(2) INSPECTION FEE.—A registration condi-
7 tion is that the exporter involved pays a fee to the
8 Secretary in accordance with this subsection. Such
9 fee shall be paid not later than October 1 and April
10 1 of each fiscal year in the amount provided for
11 under paragraph (3).

12 “(3) AMOUNT OF INSPECTION FEE.—

13 “(A) AGGREGATE TOTAL OF FEES.—Not
14 later than 30 days before the start of each fis-
15 cal year, the Secretary, in consultation with the
16 Secretary of Homeland Security and the Sec-
17 retary of the Treasury, shall establish an aggre-
18 gate total of fees to be collected under para-
19 graph (2) for exporters for that fiscal year that
20 is sufficient, and not more than necessary, to
21 pay the costs for that fiscal year of admin-
22 istering this section with respect to registered
23 exporters, including the costs associated with—

24 “(i) inspecting the facilities of reg-
25 istered exporters, and of other entities in

1 the chain of custody of a qualifying drug
2 as necessary, under subsection (d)(3);

3 “(ii) developing, implementing, and
4 operating under such subsection a system
5 to screen marks on shipments of qualifying
6 drugs under subsection (a) that indicate
7 compliance with all registration conditions,
8 when such shipments are offered for im-
9 port into the United States; and

10 “(iii) screening such markings, and
11 inspecting such shipments as necessary,
12 when offered for import into the United
13 States to determine if such a shipment
14 should be refused admission under sub-
15 section (g)(5).

16 “(B) LIMITATION.—Subject to subpara-
17 graph (C), the aggregate total of fees collected
18 under paragraph (2) for a fiscal year shall not
19 exceed 2.5 percent of the total price of quali-
20 fying drugs imported during that fiscal year
21 into the United States by registered exporters
22 under subsection (a).

23 “(C) TOTAL PRICE OF DRUGS.—

24 “(i) ESTIMATE.—For the purposes of
25 complying with the limitation described in

1 subparagraph (B) when establishing under
2 subparagraph (A) the aggregate total of
3 fees to be collected under paragraph (2)
4 for a fiscal year, the Secretary shall esti-
5 mate the total price of qualifying drugs im-
6 ported into the United States by registered
7 exporters during that fiscal year by adding
8 the total price of qualifying drugs exported
9 by each registered exporter during the 6-
10 month period from January 1 through
11 June 30 of the previous fiscal year, as re-
12 ported to the Secretary by each registered
13 exporter under subsection (b)(1)(I)(iv).

14 “(ii) CALCULATION.—Not later than
15 March 1 of the fiscal year that follows the
16 fiscal year for which the estimate under
17 clause (i) is made, the Secretary shall cal-
18 culate the total price of qualifying drugs
19 imported into the United States by reg-
20 istered exporters during that fiscal year by
21 adding the total price of qualifying drugs
22 exported by each registered exporter dur-
23 ing that fiscal year, as reported to the Sec-
24 retary by each registered exporter under
25 subsection (b)(1)(I)(iv).

1 “(iii) ADJUSTMENT.—If the total
2 price of qualifying drugs imported into the
3 United States by registered exporters dur-
4 ing a fiscal year as calculated under clause
5 (ii) is less than the aggregate total of fees
6 collected under paragraph (2) for that fis-
7 cal year, the Secretary shall provide for a
8 pro-rata reduction in the fee due from each
9 registered exporter on April 1 of the subse-
10 quent fiscal year so that the limitation de-
11 scribed in subparagraph (B) is observed.

12 “(D) INDIVIDUAL EXPORTER FEE.—Sub-
13 ject to the limitation described in subparagraph
14 (B), the fee under paragraph (2) to be paid on
15 October 1 and April 1 by an exporter shall be
16 an amount that is proportional to a reasonable
17 estimate by the Secretary of the semiannual
18 share of the exporter of the volume of quali-
19 fying drugs exported by exporters under sub-
20 section (a).

21 “(4) USE OF FEES.—

22 “(A) IN GENERAL.—Subject to appropria-
23 tions Acts, fees collected by the Secretary under
24 paragraphs (1) and (2) shall be credited to the
25 appropriation account for salaries and expenses

1 of the Food and Drug Administration until ex-
2 pended (without fiscal year limitation), and the
3 Secretary may, in consultation with the Sec-
4 retary of Homeland Security and the Secretary
5 of the Treasury, transfer some proportion of
6 such fees to the appropriation account for sala-
7 ries and expenses of the Bureau of Customs
8 and Border Protection until expended (without
9 fiscal year limitation).

10 “(B) SOLE PURPOSE.—Fees collected by
11 the Secretary under paragraphs (1) and (2) are
12 only available to the Secretary and, if trans-
13 ferred, to the Secretary of Homeland Security,
14 and are for the sole purpose of paying the costs
15 referred to in paragraph (3)(A).

16 “(5) COLLECTION OF FEES.—In any case where
17 the Secretary does not receive payment of a fee as-
18 sessed under paragraph (1) or (2) within 30 days
19 after it is due, such fee shall be treated as a claim
20 of the United States Government subject to sub-
21 chapter II of chapter 37 of title 31, United States
22 Code.

23 “(g) COMPLIANCE WITH SECTION 801(a).—

24 “(1) IN GENERAL.—A registration condition is
25 that each qualifying drug exported under subsection

1 (a) by the registered exporter involved or imported
2 under subsection (a) by the registered importer in-
3 volved is in compliance with the standards referred
4 to in section 801(a) regarding admission of the drug
5 into the United States, subject to paragraphs (2),
6 (3), and (4).

7 “(2) SECTION 505; APPROVAL STATUS.—

8 “(A) IN GENERAL.—A qualifying drug that
9 is imported or offered for import under sub-
10 section (a) shall comply with the conditions es-
11 tablished in the approved application under sec-
12 tion 505(b) for the U.S. label drug as described
13 under this subsection.

14 “(B) NOTICE BY MANUFACTURER; GEN-
15 ERAL PROVISIONS.—

16 “(i) IN GENERAL.—The person that
17 manufactures a qualifying drug that is, or
18 will be, introduced for commercial distribu-
19 tion in a permitted country shall in accord-
20 ance with this paragraph submit to the
21 Secretary a notice that—

22 “(I) includes each difference in
23 the qualifying drug from a condition
24 established in the approved applica-
25 tion for the U.S. label drug beyond—

1 “(aa) the variations provided
2 for in the application; and

3 “(bb) any difference in label-
4 ing (except ingredient labeling);
5 or

6 “(II) states that there is no dif-
7 ference in the qualifying drug from a
8 condition established in the approved
9 application for the U.S. label drug be-
10 yond—

11 “(aa) the variations provided
12 for in the application; and

13 “(bb) any difference in label-
14 ing (except ingredient labeling).

15 “(ii) INFORMATION IN NOTICE.—A
16 notice under clause (i)(I) shall include the
17 information that the Secretary may require
18 under section 506A, any additional infor-
19 mation the Secretary may require (which
20 may include data on bioequivalence if such
21 data are not required under section 506A),
22 and, with respect to the permitted country
23 that approved the qualifying drug for com-
24 mercial distribution, or with respect to

1 which such approval is sought, include the
2 following:

3 “(I) The date on which the quali-
4 fying drug with such difference was,
5 or will be, introduced for commercial
6 distribution in the permitted country.

7 “(II) Information demonstrating
8 that the person submitting the notice
9 has also notified the government of
10 the permitted country in writing that
11 the person is submitting to the Sec-
12 retary a notice under clause (i)(I),
13 which notice describes the difference
14 in the qualifying drug from a condi-
15 tion established in the approved appli-
16 cation for the U.S. label drug.

17 “(III) The information that the
18 person submitted or will submit to the
19 government of the permitted country
20 for purposes of obtaining approval for
21 commercial distribution of the drug in
22 the country which, if in a language
23 other than English, shall be accom-
24 panied by an English translation
25 verified to be complete and accurate,

1 with the name, address, and a brief
2 statement of the qualifications of the
3 person that made the translation.

4 “(iii) CERTIFICATIONS.—The chief ex-
5 ecutive officer and the chief medical officer
6 of the manufacturer involved shall each
7 certify in the notice under clause (i) that—

8 “(I) the information provided in
9 the notice is complete and true; and

10 “(II) a copy of the notice has
11 been provided to the Federal Trade
12 Commission and to the State attor-
13 neys general.

14 “(iv) FEE.—If a notice submitted
15 under clause (i) includes a difference that
16 would, under section 506A, require the
17 submission of a supplemental application if
18 made as a change to the U.S. label drug,
19 the person that submits the notice shall
20 pay to the Secretary a fee in the same
21 amount as would apply if the person were
22 paying a fee pursuant to section
23 736(a)(1)(A)(ii). Subject to appropriations
24 Acts, fees collected by the Secretary under
25 the preceding sentence are available only to

1 the Secretary and are for the sole purpose
2 of paying the costs of reviewing notices
3 submitted under clause (i).

4 “(v) TIMING OF SUBMISSION OF NO-
5 TICES.—

6 “(I) PRIOR APPROVAL NO-
7 TICES.—A notice under clause (i) to
8 which subparagraph (C) applies shall
9 be submitted to the Secretary not
10 later than 120 days before the quali-
11 fying drug with the difference is intro-
12 duced for commercial distribution in a
13 permitted country, unless the country
14 requires that distribution of the quali-
15 fying drug with the difference begin
16 less than 120 days after the country
17 requires the difference.

18 “(II) OTHER APPROVAL NO-
19 TICES.—A notice under clause (i) to
20 which subparagraph (D) applies shall
21 be submitted to the Secretary not
22 later than the day on which the quali-
23 fying drug with the difference is intro-
24 duced for commercial distribution in a
25 permitted country.

1 “(III) OTHER NOTICES.—A no-
2 tice under clause (i) to which subpara-
3 graph (E) applies shall be submitted
4 to the Secretary on the date that the
5 qualifying drug is first introduced for
6 commercial distribution in a permitted
7 country and annually thereafter.

8 “(vi) REVIEW BY SECRETARY.—

9 “(I) IN GENERAL.—In this para-
10 graph, the difference in a qualifying
11 drug that is submitted in a notice
12 under clause (i) from the U.S. label
13 drug shall be treated by the Secretary
14 as if it were a manufacturing change
15 to the U.S. label drug under section
16 506A.

17 “(II) STANDARD OF REVIEW.—
18 Except as provided in subclause (III),
19 the Secretary shall review and approve
20 or disapprove the difference in a no-
21 tice submitted under clause (i), if re-
22 quired under section 506A, using the
23 safe and effective standard for ap-
24 proving or disapproving a manufac-
25 turing change under section 506A.

1 “(III) BIOEQUIVALENCE.—If the
2 Secretary would approve the dif-
3 ference in a notice submitted under
4 clause (i) using the safe and effective
5 standard under section 506A and if
6 the Secretary determines that the
7 qualifying drug is not bioequivalent to
8 the U.S. label drug, the Secretary
9 shall—

10 “(aa) include in the labeling
11 provided under paragraph (3) a
12 prominent advisory that the
13 qualifying drug is safe and effec-
14 tive but is not bioequivalent to
15 the U.S. label drug if the Sec-
16 retary determines that such an
17 advisory is necessary for health
18 care practitioners and patients to
19 use the qualifying drug safely
20 and effectively; or

21 “(bb) decline to approve the
22 difference if the Secretary deter-
23 mines that the availability of
24 both the qualifying drug and the

1 U.S. label drug would pose a
2 threat to the public health.

3 “(IV) REVIEW BY THE SEC-
4 RETARY.—The Secretary shall review
5 and approve or disapprove the dif-
6 ference in a notice submitted under
7 clause (i), if required under section
8 506A, not later than 120 days after
9 the date on which the notice is sub-
10 mitted.

11 “(V) ESTABLISHMENT INSPEC-
12 TION.—If review of such difference
13 would require an inspection of the es-
14 tablishment in which the qualifying
15 drug is manufactured—

16 “(aa) such inspection by the
17 Secretary shall be authorized;
18 and

19 “(bb) the Secretary may rely
20 on a satisfactory report of a good
21 manufacturing practice inspec-
22 tion of the establishment from a
23 permitted country whose regu-
24 latory system the Secretary rec-
25 ognizes as equivalent under a

1 mutual recognition agreement, as
2 provided under section 510(i)(3),
3 section 803, or part 26 of title
4 21, Code of Federal Regulations
5 (or any corresponding successor
6 rule or regulation).

7 “(vii) PUBLICATION OF INFORMATION
8 ON NOTICES.—

9 “(I) IN GENERAL.—Through the
10 Internet website of the Food and
11 Drug Administration and a toll-free
12 telephone number, the Secretary shall
13 readily make available to the public a
14 list of notices submitted under clause
15 (i).

16 “(II) CONTENTS.—The list under
17 subclause (I) shall include the date on
18 which a notice is submitted and
19 whether—

20 “(aa) a notice is under re-
21 view;

22 “(bb) the Secretary has or-
23 dered that importation of the
24 qualifying drug from a permitted
25 country cease; or

1 “(cc) the importation of the
2 drug is permitted under sub-
3 section (a).

4 “(III) UPDATE.—The Secretary
5 shall promptly update the Internet
6 website with any changes to the list.

7 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
8 ING PRIOR APPROVAL.—In the case of a notice
9 under subparagraph (B)(i) that includes a dif-
10 ference that would, under section 506A(c) or
11 (d)(3)(B)(i), require the approval of a supple-
12 mental application before the difference could
13 be made to the U.S. label drug the following
14 shall occur:

15 “(i) Promptly after the notice is sub-
16 mitted, the Secretary shall notify reg-
17 istered exporters, registered importers, the
18 Federal Trade Commission, and the State
19 attorneys general that the notice has been
20 submitted with respect to the qualifying
21 drug involved.

22 “(ii) If the Secretary has not made a
23 determination whether such a supple-
24 mental application regarding the U.S. label
25 drug would be approved or disapproved by

1 the date on which the qualifying drug in-
2 volved is to be introduced for commercial
3 distribution in a permitted country, the
4 Secretary shall—

5 “(I) order that the importation of
6 the qualifying drug involved from the
7 permitted country not begin until the
8 Secretary completes review of the no-
9 tice; and

10 “(II) promptly notify registered
11 exporters, registered importers, the
12 Federal Trade Commission, and the
13 State attorneys general of the order.

14 “(iii) If the Secretary determines that
15 such a supplemental application regarding
16 the U.S. label drug would not be approved,
17 the Secretary shall—

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country cease, or provide
21 that an order under clause (ii), if any,
22 remains in effect;

23 “(II) notify the permitted coun-
24 try that approved the qualifying drug

1 for commercial distribution of the de-
2 termination; and

3 “(III) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 State attorneys general of the deter-
7 mination.

8 “(iv) If the Secretary determines that
9 such a supplemental application regarding
10 the U.S. label drug would be approved, the
11 Secretary shall—

12 “(I) vacate the order under
13 clause (ii), if any;

14 “(II) consider the difference to
15 be a variation provided for in the ap-
16 proved application for the U.S. label
17 drug;

18 “(III) permit importation of the
19 qualifying drug under subsection (a);
20 and

21 “(IV) promptly notify registered
22 exporters, registered importers, the
23 Federal Trade Commission, and the
24 State attorneys general of the deter-
25 mination.

1 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
2 QUIRING PRIOR APPROVAL.—In the case of a
3 notice under subparagraph (B)(i) that includes
4 a difference that would, under section
5 506A(d)(3)(B)(ii), not require the approval of a
6 supplemental application before the difference
7 could be made to the U.S. label drug the fol-
8 lowing shall occur:

9 “(i) During the period in which the
10 notice is being reviewed by the Secretary,
11 the authority under this subsection to im-
12 port the qualifying drug involved continues
13 in effect.

14 “(ii) If the Secretary determines that
15 such a supplemental application regarding
16 the U.S. label drug would not be approved,
17 the Secretary shall—

18 “(I) order that the importation of
19 the qualifying drug involved from the
20 permitted country cease;

21 “(II) notify the permitted coun-
22 try that approved the qualifying drug
23 for commercial distribution of the de-
24 termination; and

1 “(III) promptly notify registered
2 exporters, registered importers, the
3 Federal Trade Commission, and the
4 State attorneys general of the deter-
5 mination.

6 “(iii) If the Secretary determines that
7 such a supplemental application regarding
8 the U.S. label drug would be approved, the
9 difference shall be considered to be a vari-
10 ation provided for in the approved applica-
11 tion for the U.S. label drug.

12 “(E) NOTICE; DRUG DIFFERENCE NOT RE-
13 QUIRING APPROVAL; NO DIFFERENCE.—In the
14 case of a notice under subparagraph (B)(i) that
15 includes a difference for which, under section
16 506A(d)(1)(A), a supplemental application
17 would not be required for the difference to be
18 made to the U.S. label drug, or that states that
19 there is no difference, the Secretary—

20 “(i) shall consider such difference to
21 be a variation provided for in the approved
22 application for the U.S. label drug;

23 “(ii) may not order that the importa-
24 tion of the qualifying drug involved cease;
25 and

1 “(iii) shall promptly notify registered
2 exporters and registered importers.

3 “(F) DIFFERENCES IN ACTIVE INGRE-
4 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
5 FORM, OR STRENGTH.—

6 “(i) IN GENERAL.—A person who
7 manufactures a drug approved under sec-
8 tion 505(b) shall submit an application
9 under section 505(b) for approval of an-
10 other drug that is manufactured for dis-
11 tribution in a permitted country by or for
12 the person that manufactures the drug ap-
13 proved under section 505(b) if—

14 “(I) there is no qualifying drug
15 in commercial distribution in per-
16 mitted countries whose combined pop-
17 ulation represents at least 50 percent
18 of the total population of all permitted
19 countries with the same active ingre-
20 dient or ingredients, route of adminis-
21 tration, dosage form, and strength as
22 the drug approved under section
23 505(b); and

24 “(II) each active ingredient of
25 the other drug is related to an active

1 ingredient of the drug approved under
2 section 505(b), as defined in clause
3 (v).

4 “(ii) APPLICATION UNDER SECTION
5 505(b).—The application under section
6 505(b) required under clause (i) shall—

7 “(I) request approval of the other
8 drug for the indication or indications
9 for which the drug approved under
10 section 505(b) is labeled;

11 “(II) include the information that
12 the person submitted to the govern-
13 ment of the permitted country for
14 purposes of obtaining approval for
15 commercial distribution of the other
16 drug in that country, which if in a
17 language other than English, shall be
18 accompanied by an English trans-
19 lation verified to be complete and ac-
20 curate, with the name, address, and a
21 brief statement of the qualifications of
22 the person that made the translation;

23 “(III) include a right of reference
24 to the application for the drug ap-
25 proved under section 505(b); and

1 “(IV) include such additional in-
2 formation as the Secretary may re-
3 quire.

4 “(iii) TIMING OF SUBMISSION OF AP-
5 PPLICATION.—An application under section
6 505(b) required under clause (i) shall be
7 submitted to the Secretary not later than
8 the day on which the information referred
9 to in clause (ii)(II) is submitted to the gov-
10 ernment of the permitted country.

11 “(iv) NOTICE OF DECISION ON APPLI-
12 CATION.—The Secretary shall promptly no-
13 tify registered exporters, registered import-
14 ers, the Federal Trade Commission, and
15 the State attorneys general of a determina-
16 tion to approve or to disapprove an appli-
17 cation under section 505(b) required under
18 clause (i).

19 “(v) RELATED ACTIVE INGREDI-
20 ENTS.—For purposes of clause (i)(II), 2
21 active ingredients are related if they are—

22 “(I) the same; or

23 “(II) different salts, esters, or
24 complexes of the same moiety.

25 “(3) SECTION 502; LABELING.—

1 “(A) IMPORTATION BY REGISTERED IM-
2 PORTER.—

3 “(i) IN GENERAL.—In the case of a
4 qualifying drug that is imported or offered
5 for import by a registered importer, such
6 drug shall be considered to be in compli-
7 ance with section 502 and the labeling re-
8 quirements under the approved application
9 for the U.S. label drug if the qualifying
10 drug bears—

11 “(I) a copy of the labeling ap-
12 proved for the U.S. label drug under
13 section 505, without regard to wheth-
14 er the copy bears any trademark in-
15 volved;

16 “(II) the name of the manufac-
17 turer and location of the manufac-
18 turer;

19 “(III) the lot number assigned by
20 the manufacturer;

21 “(IV) the name, location, and
22 registration number of the importer;
23 and

1 “(V) the National Drug Code
2 number assigned to the qualifying
3 drug by the Secretary.

4 “(ii) REQUEST FOR COPY OF THE LA-
5 BELING.—The Secretary shall provide such
6 copy to the registered importer involved,
7 upon request of the importer.

8 “(iii) REQUESTED LABELING.—The
9 labeling provided by the Secretary under
10 clause (ii) shall—

11 “(I) include the established
12 name, as defined in section 502(e)(3),
13 for each active ingredient in the quali-
14 fying drug;

15 “(II) not include the proprietary
16 name of the U.S. label drug or any
17 active ingredient thereof;

18 “(III) if required under para-
19 graph (2)(B)(vi)(III), a prominent ad-
20 visory that the qualifying drug is safe
21 and effective but not bioequivalent to
22 the U.S. label drug; and

23 “(IV) if the inactive ingredients
24 of the qualifying drug are different

1 from the inactive ingredients for the
2 U.S. label drug, include—

3 “(aa) a prominent notice
4 that the ingredients of the quali-
5 fying drug differ from the ingre-
6 dients of the U.S. label drug and
7 that the qualifying drug must be
8 dispensed with an advisory to
9 people with allergies about this
10 difference and a list of ingredi-
11 ents; and

12 “(bb) a list of the ingredi-
13 ents of the qualifying drug as
14 would be required under section
15 502(e).

16 “(B) IMPORTATION BY INDIVIDUAL.—

17 “(i) IN GENERAL.—In the case of a
18 qualifying drug that is imported or offered
19 for import by a registered exporter to an
20 individual, such drug shall be considered to
21 be in compliance with section 502 and the
22 labeling requirements under the approved
23 application for the U.S. label drug if the
24 packaging and labeling of the qualifying
25 drug complies with all applicable regula-

1 tions promulgated under sections 3 and 4
2 of the Poison Prevention Packaging Act of
3 1970 (15 U.S.C. 1471 et seq.) and the la-
4 beling of the qualifying drug includes—

5 “(I) directions for use by the
6 consumer;

7 “(II) the lot number assigned by
8 the manufacturer;

9 “(III) the name and registration
10 number of the exporter;

11 “(IV) if required under para-
12 graph (2)(B)(vi)(III), a prominent ad-
13 visory that the drug is safe and effec-
14 tive but not bioequivalent to the U.S.
15 label drug;

16 “(V) if the inactive ingredients of
17 the drug are different from the inac-
18 tive ingredients for the U.S. label
19 drug—

20 “(aa) a prominent advisory
21 that persons with an allergy
22 should check the ingredient list
23 of the drug because the ingredi-
24 ents of the drug differ from the

1 ingredients of the U.S. label
2 drug; and

3 “(bb) a list of the ingredi-
4 ents of the drug as would be re-
5 quired under section 502(e); and

6 “(VI) a copy of any special label-
7 ing that would be required by the Sec-
8 retary had the U.S. label drug been
9 dispensed by a pharmacist in the
10 United States, without regard to
11 whether the special labeling bears any
12 trademark involved.

13 “(ii) PACKAGING.—A qualifying drug
14 offered for import to an individual by an
15 exporter under this section that is pack-
16 aged in a unit-of-use container (as those
17 items are defined in the United States
18 Pharmacopeia and National Formulary)
19 shall not be repackaged, provided that—

20 “(I) the packaging complies with
21 all applicable regulations under sec-
22 tions 3 and 4 of the Poison Preven-
23 tion Packaging Act of 1970 (15
24 U.S.C. 1471 et seq.); or

1 “(II) the consumer consents to
2 waive the requirements of such Act,
3 after being informed that the pack-
4 aging does not comply with such Act
5 and that the exporter will provide the
6 drug in packaging that is compliant at
7 no additional cost.

8 “(iii) REQUEST FOR COPY OF SPECIAL
9 LABELING AND INGREDIENT LIST.—The
10 Secretary shall provide to the registered
11 exporter involved a copy of the special la-
12 beling, the advisory, and the ingredient list
13 described under clause (i), upon request of
14 the exporter.

15 “(iv) REQUESTED LABELING AND IN-
16 GREDIENT LIST.—The labeling and ingre-
17 dient list provided by the Secretary under
18 clause (iii) shall—

19 “(I) include the established
20 name, as defined in section 502(e)(3),
21 for each active ingredient in the drug;
22 and

23 “(II) not include the proprietary
24 name of the U.S. label drug or any
25 active ingredient thereof.

1 “(4) SECTION 501; ADULTERATION.—A quali-
2 fying drug that is imported or offered for import
3 under subsection (a) shall be considered to be in
4 compliance with section 501 if the drug is in compli-
5 ance with subsection (c).

6 “(5) STANDARDS FOR REFUSING ADMISSION.—
7 A drug exported under subsection (a) from a reg-
8 istered exporter or imported by a registered importer
9 may be refused admission into the United States if
10 1 or more of the following applies:

11 “(A) The drug is not a qualifying drug.

12 “(B) A notice for the drug required under
13 paragraph (2)(B) has not been submitted to the
14 Secretary.

15 “(C) The Secretary has ordered that im-
16 portation of the drug from the permitted coun-
17 try cease under paragraph (2) (C) or (D).

18 “(D) The drug does not comply with para-
19 graph (3) or (4).

20 “(E) The shipping container appears dam-
21 aged in a way that may affect the strength,
22 quality, or purity of the drug.

23 “(F) The Secretary becomes aware that—

24 “(i) the drug may be counterfeit;

1 “(ii) the drug may have been pre-
2 pared, packed, or held under insanitary
3 conditions; or

4 “(iii) the methods used in, or the fa-
5 cilities or controls used for, the manufac-
6 turing, processing, packing, or holding of
7 the drug do not conform to good manufac-
8 turing practice.

9 “(G) The Secretary has obtained an in-
10 junction under section 302 that prohibits the
11 distribution of the drug in interstate commerce.

12 “(H) The Secretary has under section
13 505(e) withdrawn approval of the drug.

14 “(I) The manufacturer of the drug has in-
15 stituted a recall of the drug.

16 “(J) If the drug is imported or offered for
17 import by a registered importer without submis-
18 sion of a notice in accordance with subsection
19 (d)(4).

20 “(K) If the drug is imported or offered for
21 import from a registered exporter to an indi-
22 vidual and 1 or more of the following applies:

23 “(i) The shipping container for such
24 drug does not bear the markings required
25 under subsection (d)(2).

1 “(ii) The markings on the shipping
2 container appear to be counterfeit.

3 “(iii) The shipping container or mark-
4 ings appear to have been tampered with.

5 “(h) EXPORTER LICENSURE IN PERMITTED COUN-
6 TRY.—A registration condition is that the exporter in-
7 volved agrees that a qualifying drug will be exported to
8 an individual only if the Secretary has verified that—

9 “(1) the exporter is authorized under the law of
10 the permitted country in which the exporter is lo-
11 cated to dispense prescription drugs; and

12 “(2) the exporter employs persons that are li-
13 censed under the law of the permitted country in
14 which the exporter is located to dispense prescription
15 drugs in sufficient number to dispense safely the
16 drugs exported by the exporter to individuals, and
17 the exporter assigns to those persons responsibility
18 for dispensing such drugs to individuals.

19 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
20 TION.—

21 “(1) IN GENERAL.—For purposes of subsection
22 (a)(2)(B), the importation of a qualifying drug by
23 an individual is in accordance with this subsection if
24 the following conditions are met:

1 “(A) The drug is accompanied by a copy of
2 a prescription for the drug, which prescrip-
3 tion—

4 “(i) is valid under applicable Federal
5 and State laws; and

6 “(ii) was issued by a practitioner who,
7 under the law of a State of which the indi-
8 vidual is a resident, or in which the indi-
9 vidual receives care from the practitioner
10 who issues the prescription, is authorized
11 to administer prescription drugs.

12 “(B) The drug is accompanied by a copy
13 of the documentation that was required under
14 the law or regulations of the permitted country
15 in which the exporter is located, as a condition
16 of dispensing the drug to the individual.

17 “(C) The copies referred to in subpara-
18 graphs (A)(i) and (B) are marked in a manner
19 sufficient—

20 “(i) to indicate that the prescription,
21 and the equivalent document in the per-
22 mitted country in which the exporter is lo-
23 cated, have been filled; and

24 “(ii) to prevent a duplicative filling by
25 another pharmacist.

1 “(D) The individual has provided to the
2 registered exporter a complete list of all drugs
3 used by the individual for review by the individ-
4 uals who dispense the drug.

5 “(E) The quantity of the drug does not ex-
6 ceed a 90-day supply.

7 “(F) The drug is not an ineligible subpart
8 H drug. For purposes of this section, a pre-
9 scription drug is an ‘ineligible subpart H drug’
10 if the drug was approved by the Secretary
11 under subpart H of part 314 of title 21, Code
12 of Federal Regulations (relating to accelerated
13 approval), with restrictions under section 520 of
14 such part to assure safe use, and the Secretary
15 has published in the Federal Register a notice
16 that the Secretary has determined that good
17 cause exists to prohibit the drug from being im-
18 ported pursuant to this subsection.

19 “(2) NOTICE REGARDING DRUG REFUSED AD-
20 MISSION.—If a registered exporter ships a drug to
21 an individual pursuant to subsection (a)(2)(B) and
22 the drug is refused admission to the United States,
23 a written notice shall be sent to the individual and
24 to the exporter that informs the individual and the

1 exporter of such refusal and the reason for the re-
2 fusar.

3 “(j) MAINTENANCE OF RECORDS AND SAMPLES.—

4 “(1) IN GENERAL.—A registration condition is
5 that the importer or exporter involved shall—

6 “(A) maintain records required under this
7 section for not less than 2 years; and

8 “(B) maintain samples of each lot of a
9 qualifying drug required under this section for
10 not more than 2 years.

11 “(2) PLACE OF RECORD MAINTENANCE.—The
12 records described under paragraph (1) shall be
13 maintained—

14 “(A) in the case of an importer, at the
15 place of business of the importer at which the
16 importer initially receives the qualifying drug
17 after importation; or

18 “(B) in the case of an exporter, at the fa-
19 cility from which the exporter ships the quali-
20 fying drug to the United States.

21 “(k) DRUG RECALLS.—

22 “(1) MANUFACTURERS.—A person that manu-
23 factures a qualifying drug imported from a per-
24 mitted country under this section shall promptly in-
25 form the Secretary—

1 “(A) if the drug is recalled or withdrawn
2 from the market in a permitted country;

3 “(B) how the drug may be identified, in-
4 cluding lot number; and

5 “(C) the reason for the recall or with-
6 drawal.

7 “(2) SECRETARY.—With respect to each per-
8 mitted country, the Secretary shall—

9 “(A) enter into an agreement with the gov-
10 ernment of the country to receive information
11 about recalls and withdrawals of qualifying
12 drugs in the country; or

13 “(B) monitor recalls and withdrawals of
14 qualifying drugs in the country using any infor-
15 mation that is available to the public in any
16 media.

17 “(3) NOTICE.—The Secretary may notify, as
18 appropriate, registered exporters, registered import-
19 ers, wholesalers, pharmacies, or the public of a recall
20 or withdrawal of a qualifying drug in a permitted
21 country.

22 “(1) DRUG LABELING AND PACKAGING.—

23 “(1) IN GENERAL.—When a qualifying drug
24 that is imported into the United States by an im-
25 porter under subsection (a) is dispensed by a phar-

1 macist to an individual, the pharmacist shall provide
2 that the packaging and labeling of the drug complies
3 with all applicable regulations promulgated under
4 sections 3 and 4 of the Poison Prevention Packaging
5 Act of 1970 (15 U.S.C. 1471 et seq.) and shall in-
6 clude with any other labeling provided to the indi-
7 vidual the following:

8 “(A) The lot number assigned by the man-
9 ufacturer.

10 “(B) The name and registration number of
11 the importer.

12 “(C) If required under paragraph
13 (2)(B)(vi)(III) of subsection (g), a prominent
14 advisory that the drug is safe and effective but
15 not bioequivalent to the U.S. label drug.

16 “(D) If the inactive ingredients of the drug
17 are different from the inactive ingredients for
18 the U.S. label drug—

19 “(i) a prominent advisory that persons
20 with allergies should check the ingredient
21 list of the drug because the ingredients of
22 the drug differ from the ingredients of the
23 U.S. label drug; and

1 “(ii) a list of the ingredients of the
2 drug as would be required under section
3 502(e).

4 “(2) PACKAGING.—A qualifying drug that is
5 packaged in a unit-of-use container (as those terms
6 are defined in the United States Pharmacopeia and
7 National Formulary) shall not be repackaged, pro-
8 vided that—

9 “(A) the packaging complies with all appli-
10 cable regulations under sections 3 and 4 of the
11 Poison Prevention Packaging Act of 1970 (15
12 U.S.C. 1471 et seq.); or

13 “(B) the consumer consents to waive the
14 requirements of such Act, after being informed
15 that the packaging does not comply with such
16 Act and that the pharmacist will provide the
17 drug in packaging that is compliant at no addi-
18 tional cost.

19 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-
20 standing any other provision of this section, this section
21 does not authorize the importation into the United States
22 of a qualifying drug donated or otherwise supplied for free
23 or at nominal cost by the manufacturer of the drug to
24 a charitable or humanitarian organization, including the

1 United Nations and affiliates, or to a government of a for-
2 eign country.

3 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
4 TICES.—

5 “(1) IN GENERAL.—It is unlawful for a manu-
6 facturer, directly or indirectly (including by being a
7 party to a licensing agreement or other agreement),
8 to—

9 “(A) discriminate by charging a higher
10 price for a prescription drug sold to a registered
11 exporter or other person in a permitted country
12 that exports a qualifying drug to the United
13 States under this section than the price that is
14 charged, inclusive of rebates or other incentives
15 to the permitted country or other person, to an-
16 other person that is in the same country and
17 that does not export a qualifying drug into the
18 United States under this section;

19 “(B) discriminate by charging a higher
20 price for a prescription drug sold to a registered
21 importer or other person that distributes, sells,
22 or uses a qualifying drug imported into the
23 United States under this section than the price
24 that is charged to another person in the United
25 States that does not import a qualifying drug

1 under this section, or that does not distribute,
2 sell, or use such a drug;

3 “(C) discriminate by denying, restricting,
4 or delaying supplies of a prescription drug to a
5 registered exporter or other person in a per-
6 mitted country that exports a qualifying drug to
7 the United States under this section or to a
8 registered importer or other person that distrib-
9 utes, sells, or uses a qualifying drug imported
10 into the United States under this section;

11 “(D) discriminate by publicly, privately, or
12 otherwise refusing to do business with a reg-
13 istered exporter or other person in a permitted
14 country that exports a qualifying drug to the
15 United States under this section or with a reg-
16 istered importer or other person that distrib-
17 utes, sells, or uses a qualifying drug imported
18 into the United States under this section;

19 “(E) knowingly fail to submit a notice
20 under subsection (g)(2)(B)(i), knowingly fail to
21 submit such a notice on or before the date spec-
22 ified in subsection (g)(2)(B)(v) or as otherwise
23 required under subsection (e) (3), (4), and (5)
24 of section 4 of the Pharmaceutical Market Ac-
25 cess and Drug Safety Act of 2007, knowingly

1 submit such a notice that makes a materially
2 false, fictitious, or fraudulent statement, or
3 knowingly fail to provide promptly any informa-
4 tion requested by the Secretary to review such
5 a notice;

6 “(F) knowingly fail to submit an applica-
7 tion required under subsection (g)(2)(F), know-
8 ingly fail to submit such an application on or
9 before the date specified in subsection
10 (g)(2)(F)(ii), knowingly submit such an applica-
11 tion that makes a materially false, fictitious, or
12 fraudulent statement, or knowingly fail to pro-
13 vide promptly any information requested by the
14 Secretary to review such an application;

15 “(G) cause there to be a difference (includ-
16 ing a difference in active ingredient, route of
17 administration, dosage form, strength, formula-
18 tion, manufacturing establishment, manufac-
19 turing process, or person that manufactures the
20 drug) between a prescription drug for distribu-
21 tion in the United States and the drug for dis-
22 tribution in a permitted country;

23 “(H) refuse to allow an inspection author-
24 ized under this section of an establishment that
25 manufactures a qualifying drug that is, or will

1 be, introduced for commercial distribution in a
2 permitted country;

3 “(I) fail to conform to the methods used
4 in, or the facilities used for, the manufacturing,
5 processing, packing, or holding of a qualifying
6 drug that is, or will be, introduced for commer-
7 cial distribution in a permitted country to good
8 manufacturing practice under this Act;

9 “(J) become a party to a licensing agree-
10 ment or other agreement related to a qualifying
11 drug that fails to provide for compliance with
12 all requirements of this section with respect to
13 such drug;

14 “(K) enter into a contract that restricts,
15 prohibits, or delays the importation of a quali-
16 fying drug under this section;

17 “(L) engage in any other action to restrict,
18 prohibit, or delay the importation of a quali-
19 fying drug under this section; or

20 “(M) engage in any other action that the
21 Federal Trade Commission determines to dis-
22 criminate against a person that engages or at-
23 tempts to engage in the importation of a quali-
24 fying drug under this section.

1 “(2) REFERRAL OF POTENTIAL VIOLATIONS.—

2 The Secretary shall promptly refer to the Federal
3 Trade Commission each potential violation of sub-
4 paragraph (E), (F), (G), (H), or (I) of paragraph
5 (1) that becomes known to the Secretary.

6 “(3) AFFIRMATIVE DEFENSE.—

7 “(A) DISCRIMINATION.—It shall be an af-
8 firmative defense to a charge that a manufac-
9 turer has discriminated under subparagraph
10 (A), (B), (C), (D), or (M) of paragraph (1) that
11 the higher price charged for a prescription drug
12 sold to a person, the denial, restriction, or delay
13 of supplies of a prescription drug to a person,
14 the refusal to do business with a person, or
15 other discriminatory activity against a person,
16 is not based, in whole or in part, on—

17 “(i) the person exporting or importing
18 a qualifying drug into the United States
19 under this section; or

20 “(ii) the person distributing, selling,
21 or using a qualifying drug imported into
22 the United States under this section.

23 “(B) DRUG DIFFERENCES.—It shall be an
24 affirmative defense to a charge that a manufac-
25 turer has caused there to be a difference de-

scribed in subparagraph (G) of paragraph (1)
that—

“(i) the difference was required by the
country in which the drug is distributed;

“(ii) the Secretary has determined
that the difference was necessary to im-
prove the safety or effectiveness of the
drug;

“(iii) the person manufacturing the
drug for distribution in the United States
has given notice to the Secretary under
subsection (g)(2)(B)(i) that the drug for
distribution in the United States is not dif-
ferent from a drug for distribution in per-
mitted countries whose combined popu-
lation represents at least 50 percent of the
total population of all permitted countries;
or

“(iv) the difference was not caused, in
whole or in part, for the purpose of re-
stricting importation of the drug into the
United States under this section.

“(4) EFFECT OF SUBSECTION.—

“(A) SALES IN OTHER COUNTRIES.—This
subsection applies only to the sale or distribu-

1 tion of a prescription drug in a country if the
2 manufacturer of the drug chooses to sell or dis-
3 tribute the drug in the country. Nothing in this
4 subsection shall be construed to compel the
5 manufacturer of a drug to distribute or sell the
6 drug in a country.

7 “(B) DISCOUNTS TO INSURERS, HEALTH
8 PLANS, PHARMACY BENEFIT MANAGERS, AND
9 COVERED ENTITIES.—Nothing in this sub-
10 section shall be construed to—

11 “(i) prevent or restrict a manufac-
12 turer of a prescription drug from providing
13 discounts to an insurer, health plan, phar-
14 macy benefit manager in the United
15 States, or covered entity in the drug dis-
16 count program under section 340B of the
17 Public Health Service Act (42 U.S.C.
18 256b) in return for inclusion of the drug
19 on a formulary;

20 “(ii) require that such discounts be
21 made available to other purchasers of the
22 prescription drug; or

23 “(iii) prevent or restrict any other
24 measures taken by an insurer, health plan,

1 or pharmacy benefit manager to encourage
2 consumption of such prescription drug.

3 “(C) CHARITABLE CONTRIBUTIONS.—

4 Nothing in this subsection shall be construed
5 to—

6 “(i) prevent a manufacturer from do-
7 nating a prescription drug, or supplying a
8 prescription drug at nominal cost, to a
9 charitable or humanitarian organization,
10 including the United Nations and affili-
11 ates, or to a government of a foreign coun-
12 try; or

13 “(ii) apply to such donations or sup-
14 plying of a prescription drug.

15 “(5) ENFORCEMENT.—

16 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-
17 TICE.—A violation of this subsection shall be
18 treated as a violation of a rule defining an un-
19 fair or deceptive act or practice prescribed
20 under section 18(a)(1)(B) of the Federal Trade
21 Commission Act (15 U.S.C. 57a(a)(1)(B)).

22 “(B) ACTIONS BY THE COMMISSION.—The
23 Federal Trade Commission—

24 “(i) shall enforce this subsection in
25 the same manner, by the same means, and

1 with the same jurisdiction, powers, and du-
2 ties as though all applicable terms and pro-
3 visions of the Federal Trade Commission
4 Act (15 U.S.C. 41 et seq.) were incor-
5 porated into and made a part of this sec-
6 tion; and

7 “(ii) may seek monetary relief three-
8 fold the damages sustained, in addition to
9 any other remedy available to the Federal
10 Trade Commission under the Federal
11 Trade Commission Act (15 U.S.C. 41 et
12 seq.).

13 “(6) ACTIONS BY STATES.—

14 “(A) IN GENERAL.—

15 “(i) CIVIL ACTIONS.—In any case in
16 which the attorney general of a State has
17 reason to believe that an interest of the
18 residents of that State have been adversely
19 affected by any manufacturer that violates
20 paragraph (1), the attorney general of a
21 State may bring a civil action on behalf of
22 the residents of the State, and persons
23 doing business in the State, in a district
24 court of the United States of appropriate
25 jurisdiction to—

1 “(I) enjoin that practice;

2 “(II) enforce compliance with
3 this subsection;

4 “(III) obtain damages, restitu-
5 tion, or other compensation on behalf
6 of residents of the State and persons
7 doing business in the State, including
8 threefold the damages; or

9 “(IV) obtain such other relief as
10 the court may consider to be appro-
11 priate.

12 “(ii) NOTICE.—

13 “(I) IN GENERAL.—Before filing
14 an action under clause (i), the attor-
15 ney general of the State involved shall
16 provide to the Federal Trade Commis-
17 sion—

18 “(aa) written notice of that
19 action; and

20 “(bb) a copy of the com-
21 plaint for that action.

22 “(II) EXEMPTION.—Subclause
23 (I) shall not apply with respect to the
24 filing of an action by an attorney gen-
25 eral of a State under this paragraph,

1 if the attorney general determines
2 that it is not feasible to provide the
3 notice described in that subclause be-
4 fore filing of the action. In such case,
5 the attorney general of a State shall
6 provide notice and a copy of the com-
7 plaint to the Federal Trade Commis-
8 sion at the same time as the attorney
9 general files the action.

10 “(B) INTERVENTION.—

11 “(i) IN GENERAL.—On receiving no-
12 tice under subparagraph (A)(ii), the Fed-
13 eral Trade Commission shall have the right
14 to intervene in the action that is the sub-
15 ject of the notice.

16 “(ii) EFFECT OF INTERVENTION.—If
17 the Federal Trade Commission intervenes
18 in an action under subparagraph (A), it
19 shall have the right—

20 “(I) to be heard with respect to
21 any matter that arises in that action;
22 and

23 “(II) to file a petition for appeal.

24 “(C) CONSTRUCTION.—For purposes of
25 bringing any civil action under subparagraph

1 (A), nothing in this subsection shall be con-
2 strued to prevent an attorney general of a State
3 from exercising the powers conferred on the at-
4 torney general by the laws of that State to—

5 “(i) conduct investigations;

6 “(ii) administer oaths or affirmations;

7 or

8 “(iii) compel the attendance of wit-
9 nesses or the production of documentary
10 and other evidence.

11 “(D) ACTIONS BY THE COMMISSION.—In
12 any case in which an action is instituted by or
13 on behalf of the Federal Trade Commission for
14 a violation of paragraph (1), a State may not,
15 during the pendency of that action, institute an
16 action under subparagraph (A) for the same
17 violation against any defendant named in the
18 complaint in that action.

19 “(E) VENUE.—Any action brought under
20 subparagraph (A) may be brought in the dis-
21 trict court of the United States that meets ap-
22 plicable requirements relating to venue under
23 section 1391 of title 28, United States Code.

24 “(F) SERVICE OF PROCESS.—In an action
25 brought under subparagraph (A), process may

1 be served in any district in which the defend-
2 ant—

3 “(i) is an inhabitant; or

4 “(ii) may be found.

5 “(G) MEASUREMENT OF DAMAGES.—In
6 any action under this paragraph to enforce a
7 cause of action under this subsection in which
8 there has been a determination that a defend-
9 ant has violated a provision of this subsection,
10 damages may be proved and assessed in the ag-
11 gregate by statistical or sampling methods, by
12 the computation of illegal overcharges or by
13 such other reasonable system of estimating ag-
14 gregate damages as the court in its discretion
15 may permit without the necessity of separately
16 proving the individual claim of, or amount of
17 damage to, persons on whose behalf the suit
18 was brought.

19 “(H) EXCLUSION ON DUPLICATIVE RE-
20 LIEF.—The district court shall exclude from the
21 amount of monetary relief awarded in an action
22 under this paragraph brought by the attorney
23 general of a State any amount of monetary re-
24 lief which duplicates amounts which have been
25 awarded for the same injury.

1 “(7) EFFECT ON ANTITRUST LAWS.—Nothing
2 in this subsection shall be construed to modify, im-
3 pair, or supersede the operation of the antitrust
4 laws. For the purpose of this subsection, the term
5 ‘antitrust laws’ has the meaning given it in the first
6 section of the Clayton Act, except that it includes
7 section 5 of the Federal Trade Commission Act to
8 the extent that such section 5 applies to unfair
9 methods of competition.

10 “(8) MANUFACTURER.—In this subsection, the
11 term ‘manufacturer’ means any entity, including any
12 affiliate or licensee of that entity, that is engaged
13 in—

14 “(A) the production, preparation, propaga-
15 tion, compounding, conversion, or processing of
16 a prescription drug, either directly or indirectly
17 by extraction from substances of natural origin,
18 or independently by means of chemical syn-
19 thesis, or by a combination of extraction and
20 chemical synthesis; or

21 “(B) the packaging, repackaging, labeling,
22 relabeling, or distribution of a prescription
23 drug.”.

24 (b) PROHIBITED ACTS.—The Federal Food, Drug,
25 and Cosmetic Act is amended—

1 (1) in section 301 (21 U.S.C. 331), by striking
2 paragraph (aa) and inserting the following:

3 “(aa)(1) The sale or trade by a pharmacist, or by
4 a business organization of which the pharmacist is a part,
5 of a qualifying drug that under section 804(a)(2)(A) was
6 imported by the pharmacist, other than—

7 “(A) a sale at retail made pursuant to dis-
8 pensing the drug to a customer of the pharmacist or
9 organization; or

10 “(B) a sale or trade of the drug to a pharmacy
11 or a wholesaler registered to import drugs under sec-
12 tion 804.

13 “(2) The sale or trade by an individual of a qualifying
14 drug that under section 804(a)(2)(B) was imported by the
15 individual.

16 “(3) The making of a materially false, fictitious, or
17 fraudulent statement or representation, or a material
18 omission, in a notice under clause (i) of section
19 804(g)(2)(B) or in an application required under section
20 804(g)(2)(F), or the failure to submit such a notice or
21 application.

22 “(4) The importation of a drug in violation of a reg-
23 istration condition or other requirement under section
24 804, the falsification of any record required to be main-
25 tained, or provided to the Secretary, under such section,

1 or the violation of any registration condition or other re-
2 quirement under such section.”; and

3 (2) in section 303(a) (21 U.S.C. 333(a)), by
4 striking paragraph (6) and inserting the following:

5 “(6) Notwithstanding subsection (a), any person that
6 knowingly violates section 301(i) (2) or (3) or section
7 301(aa)(4) shall be imprisoned not more than 10 years,
8 or fined in accordance with title 18, United States Code,
9 or both.”.

10 (c) AMENDMENT OF CERTAIN PROVISIONS.—

11 (1) IN GENERAL.—Section 801 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
13 amended by striking subsection (g) and inserting the
14 following:

15 “(g) With respect to a prescription drug that is im-
16 ported or offered for import into the United States by an
17 individual who is not in the business of such importation,
18 that is not shipped by a registered exporter under section
19 804, and that is refused admission under subsection (a),
20 the Secretary shall notify the individual that—

21 “(1) the drug has been refused admission be-
22 cause the drug was not a lawful import under sec-
23 tion 804;

24 “(2) the drug is not otherwise subject to a
25 waiver of the requirements of subsection (a);

1 “(3) the individual may under section 804 law-
2 fully import certain prescription drugs from export-
3 ers registered with the Secretary under section 804;
4 and

5 “(4) the individual can find information about
6 such importation, including a list of registered ex-
7 porters, on the Internet website of the Food and
8 Drug Administration or through a toll-free telephone
9 number required under section 804.”.

10 (2) ESTABLISHMENT REGISTRATION.—Section
11 510(i) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 360(i)) is amended in paragraph (1) by
13 inserting after “import into the United States” the
14 following: “, including a drug that is, or may be, im-
15 ported or offered for import into the United States
16 under section 804,”.

17 (3) EFFECTIVE DATE.—The amendments made
18 by this subsection shall take effect on the date that
19 is 90 days after the date of enactment of this title.

20 (d) EXHAUSTION.—

21 (1) IN GENERAL.—Section 271 of title 35,
22 United States Code, is amended—

23 (A) by redesignating subsections (h) and
24 (i) as (i) and (j), respectively; and

1 (B) by inserting after subsection (g) the
2 following:

3 “(h) It shall not be an act of infringement to use,
4 offer to sell, or sell within the United States or to import
5 into the United States any patented invention under sec-
6 tion 804 of the Federal Food, Drug, and Cosmetic Act
7 that was first sold abroad by or under authority of the
8 owner or licensee of such patent.”.

9 (2) RULE OF CONSTRUCTION.—Nothing in the
10 amendment made by paragraph (1) shall be con-
11 strued to affect the ability of a patent owner or li-
12 censee to enforce their patent, subject to such
13 amendment.

14 (e) EFFECT OF SECTION 804.—

15 (1) IN GENERAL.—Section 804 of the Federal
16 Food, Drug, and Cosmetic Act, as added by sub-
17 section (a), shall permit the importation of quali-
18 fying drugs (as defined in such section 804) into the
19 United States without regard to the status of the
20 issuance of implementing regulations—

21 (A) from exporters registered under such
22 section 804 on the date that is 90 days after
23 the date of enactment of this title; and

24 (B) from permitted countries, as defined in
25 such section 804, by importers registered under

1 such section 804 on the date that is 1 year
2 after the date of enactment of this title.

3 (2) REVIEW OF REGISTRATION BY CERTAIN EX-
4 PORTERS.—

5 (A) REVIEW PRIORITY.—In the review of
6 registrations submitted under subsection (b) of
7 such section 804, registrations submitted by en-
8 tities in Canada that are significant exporters
9 of prescription drugs to individuals in the
10 United States as of the date of enactment of
11 this title will have priority during the 90 day
12 period that begins on such date of enactment.

13 (B) PERIOD FOR REVIEW.—During such
14 90-day period, the reference in subsection
15 (b)(2)(A) of such section 804 to 90 days (relat-
16 ing to approval or disapproval of registrations)
17 is, as applied to such entities, deemed to be 30
18 days.

19 (C) LIMITATION.—That an exporter in
20 Canada exports, or has exported, prescription
21 drugs to individuals in the United States on or
22 before the date that is 90 days after the date
23 of enactment of this title shall not serve as a
24 basis, in whole or in part, for disapproving a

1 registration under such section 804 from the
2 exporter.

3 (D) FIRST YEAR LIMIT ON NUMBER OF
4 EXPORTERS.—During the 1-year period begin-
5 ning on the date of enactment of this title, the
6 Secretary of Health and Human Services (re-
7 ferred to in this section as the “Secretary”)
8 may limit the number of registered exporters
9 under such section 804 to not less than 50, so
10 long as the Secretary gives priority to those ex-
11 porters with demonstrated ability to process a
12 high volume of shipments of drugs to individ-
13 uals in the United States.

14 (E) SECOND YEAR LIMIT ON NUMBER OF
15 EXPORTERS.—During the 1-year period begin-
16 ning on the date that is 1 year after the date
17 of enactment of this title, the Secretary may
18 limit the number of registered exporters under
19 such section 804 to not less than 100, so long
20 as the Secretary gives priority to those export-
21 ers with demonstrated ability to process a high
22 volume of shipments of drugs to individuals in
23 the United States.

24 (F) FURTHER LIMIT ON NUMBER OF EX-
25 PORTERS.—During any 1-year period beginning

1 on a date that is 2 or more years after the date
2 of enactment of this title, the Secretary may
3 limit the number of registered exporters under
4 such section 804 to not less than 25 more than
5 the number of such exporters during the pre-
6 vious 1-year period, so long as the Secretary
7 gives priority to those exporters with dem-
8 onstrated ability to process a high volume of
9 shipments of drugs to individuals in the United
10 States.

11 (3) LIMITS ON NUMBER OF IMPORTERS.—

12 (A) FIRST YEAR LIMIT ON NUMBER OF IM-
13 PORTERS.—During the 1-year period beginning
14 on the date that is 1 year after the date of en-
15 actment of this title, the Secretary may limit
16 the number of registered importers under such
17 section 804 to not less than 100 (of which at
18 least a significant number shall be groups of
19 pharmacies, to the extent feasible given the ap-
20 plications submitted by such groups), so long as
21 the Secretary gives priority to those importers
22 with demonstrated ability to process a high vol-
23 ume of shipments of drugs imported into the
24 United States.

1 (B) SECOND YEAR LIMIT ON NUMBER OF
2 IMPORTERS.—During the 1-year period begin-
3 ning on the date that is 2 years after the date
4 of enactment of this title, the Secretary may
5 limit the number of registered importers under
6 such section 804 to not less than 200 (of which
7 at least a significant number shall be groups of
8 pharmacies, to the extent feasible given the ap-
9 plications submitted by such groups), so long as
10 the Secretary gives priority to those importers
11 with demonstrated ability to process a high vol-
12 ume of shipments of drugs into the United
13 States.

14 (C) FURTHER LIMIT ON NUMBER OF IM-
15 PORTERS.—During any 1-year period beginning
16 on a date that is 3 or more years after the date
17 of enactment of this title, the Secretary may
18 limit the number of registered importers under
19 such section 804 to not less than 50 more (of
20 which at least a significant number shall be
21 groups of pharmacies, to the extent feasible
22 given the applications submitted by such
23 groups) than the number of such importers
24 during the previous 1-year period, so long as
25 the Secretary gives priority to those importers

1 with demonstrated ability to process a high vol-
2 ume of shipments of drugs to the United
3 States.

4 (4) NOTICES FOR DRUGS FOR IMPORT FROM
5 CANADA.—The notice with respect to a qualifying
6 drug introduced for commercial distribution in Can-
7 ada as of the date of enactment of this title that is
8 required under subsection (g)(2)(B)(i) of such sec-
9 tion 804 shall be submitted to the Secretary not
10 later than 30 days after the date of enactment of
11 this title if—

12 (A) the U.S. label drug (as defined in such
13 section 804) for the qualifying drug is 1 of the
14 100 prescription drugs with the highest dollar
15 volume of sales in the United States based on
16 the 12 calendar month period most recently
17 completed before the date of enactment of this
18 Act; or

19 (B) the notice is a notice under subsection
20 (g)(2)(B)(i)(II) of such section 804.

21 (5) NOTICE FOR DRUGS FOR IMPORT FROM
22 OTHER COUNTRIES.—The notice with respect to a
23 qualifying drug introduced for commercial distribu-
24 tion in a permitted country other than Canada as of
25 the date of enactment of this title that is required

1 under subsection (g)(2)(B)(i) of such section 804
2 shall be submitted to the Secretary not later than
3 180 days after the date of enactment of this title
4 if—

5 (A) the U.S. label drug for the qualifying
6 drug is 1 of the 100 prescription drugs with the
7 highest dollar volume of sales in the United
8 States based on the 12 calendar month period
9 that is first completed on the date that is 120
10 days after the date of enactment of this title; or

11 (B) the notice is a notice under subsection
12 (g)(2)(B)(i)(II) of such section 804.

13 (6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

14 (A) GUIDANCE ON SUBMISSION DATES.—
15 The Secretary shall by guidance establish a se-
16 ries of submission dates for the notices under
17 subsection (g)(2)(B)(i) of such section 804 with
18 respect to qualifying drugs introduced for com-
19 mercial distribution as of the date of enactment
20 of this title and that are not required to be sub-
21 mitted under paragraph (4) or (5).

22 (B) CONSISTENT AND EFFICIENT USE OF
23 RESOURCES.—The Secretary shall establish the
24 dates described under subparagraph (A) so that
25 such notices described under subparagraph (A)

1 are submitted and reviewed at a rate that al-
2 lows consistent and efficient use of the re-
3 sources and staff available to the Secretary for
4 such reviews. The Secretary may condition the
5 requirement to submit such a notice, and the
6 review of such a notice, on the submission by a
7 registered exporter or a registered importer to
8 the Secretary of a notice that such exporter or
9 importer intends to import such qualifying drug
10 to the United States under such section 804.

11 (C) PRIORITY FOR DRUGS WITH HIGHER
12 SALES.—The Secretary shall establish the dates
13 described under subparagraph (A) so that the
14 Secretary reviews the notices described under
15 such subparagraph with respect to qualifying
16 drugs with higher dollar volume of sales in the
17 United States before the notices with respect to
18 drugs with lower sales in the United States.

19 (7) NOTICES FOR DRUGS APPROVED AFTER EF-
20 FECTIVE DATE.—The notice required under sub-
21 section (g)(2)(B)(i) of such section 804 for a quali-
22 fying drug first introduced for commercial distribu-
23 tion in a permitted country (as defined in such sec-
24 tion 804) after the date of enactment of this title
25 shall be submitted to and reviewed by the Secretary

1 as provided under subsection (g)(2)(B) of such sec-
2 tion 804, without regard to paragraph (4), (5), or
3 (6).

4 (8) REPORT.—Beginning with the first full fis-
5 cal year after the date of enactment of this title, not
6 later than 90 days after the end of each fiscal year
7 during which the Secretary reviews a notice referred
8 to in paragraph (4), (5), or (6), the Secretary shall
9 submit a report to Congress concerning the progress
10 of the Food and Drug Administration in reviewing
11 the notices referred to in paragraphs (4), (5), and
12 (6).

13 (9) USER FEES.—

14 (A) EXPORTERS.—When establishing an
15 aggregate total of fees to be collected from ex-
16 porters under subsection (f)(2) of such section
17 804, the Secretary shall, under subsection
18 (f)(3)(C)(i) of such section 804, estimate the
19 total price of drugs imported under subsection
20 (a) of such section 804 into the United States
21 by registered exporters during the first fiscal
22 year in which this title takes effect to be an
23 amount equal to the amount which bears the
24 same ratio to \$1,000,000,000 as the number of

1 days in such fiscal year during which this title
2 is effective bears to 365.

3 (B) IMPORTERS.—When establishing an
4 aggregate total of fees to be collected from im-
5 porters under subsection (e)(2) of such section
6 804, the Secretary shall, under subsection
7 (e)(3)(C)(i) of such section 804, estimate the
8 total price of drugs imported under subsection
9 (a) of such section 804 into the United States
10 by registered importers during—

11 (i) the first fiscal year in which this
12 title takes effect to be an amount equal to
13 the amount which bears the same ratio to
14 \$1,000,000,000 as the number of days in
15 such fiscal year during which this title is
16 effective bears to 365; and

17 (ii) the second fiscal year in which
18 this title is in effect to be \$3,000,000,000.

19 (C) SECOND YEAR ADJUSTMENT.—

20 (i) REPORTS.—Not later than Feb-
21 ruary 20 of the second fiscal year in which
22 this title is in effect, registered importers
23 shall report to the Secretary the total price
24 and the total volume of drugs imported to
25 the United States by the importer during

1 the 4-month period from October 1
2 through January 31 of such fiscal year.

3 (ii) REESTIMATE.—Notwithstanding
4 subsection (e)(3)(C)(ii) of such section 804
5 or subparagraph (B), the Secretary shall
6 reestimate the total price of qualifying
7 drugs imported under subsection (a) of
8 such section 804 into the United States by
9 registered importers during the second fis-
10 cal year in which this title is in effect.
11 Such reestimate shall be equal to—

12 (I) the total price of qualifying
13 drugs imported by each importer as
14 reported under clause (i); multiplied
15 by

16 (II) 3.

17 (iii) ADJUSTMENT.—The Secretary
18 shall adjust the fee due on April 1 of the
19 second fiscal year in which this title is in
20 effect, from each importer so that the ag-
21 gregate total of fees collected under sub-
22 section (e)(2) for such fiscal year does not
23 exceed the total price of qualifying drugs
24 imported under subsection (a) of such sec-
25 tion 804 into the United States by reg-

1 istered importers during such fiscal year as
2 reestimated under clause (ii).

3 (D) FAILURE TO PAY FEES.—Notwith-
4 standing any other provision of this section, the
5 Secretary may prohibit a registered importer or
6 exporter that is required to pay user fees under
7 subsection (e) or (f) of such section 804 and
8 that fails to pay such fees within 30 days after
9 the date on which it is due, from importing or
10 offering for importation a qualifying drug under
11 such section 804 until such fee is paid.

12 (E) ANNUAL REPORT.—

13 (i) FOOD AND DRUG ADMINISTRA-
14 TION.—Not later than 180 days after the
15 end of each fiscal year during which fees
16 are collected under subsection (e), (f), or
17 (g)(2)(B)(iv) of such section 804, the Sec-
18 retary shall prepare and submit to the
19 House of Representatives and the Senate a
20 report on the implementation of the au-
21 thority for such fees during such fiscal
22 year and the use, by the Food and Drug
23 Administration, of the fees collected for the
24 fiscal year for which the report is made

1 and credited to the Food and Drug Admin-
2 istration.

3 (ii) CUSTOMS AND BORDER CON-
4 TROL.—Not later than 180 days after the
5 end of each fiscal year during which fees
6 are collected under subsection (e) or (f) of
7 such section 804, the Secretary of Home-
8 land Security, in consultation with the Sec-
9 retary of the Treasury, shall prepare and
10 submit to the House of Representatives
11 and the Senate a report on the use, by the
12 Bureau of Customs and Border Protection,
13 of the fees, if any, transferred by the Sec-
14 retary to the Bureau of Customs and Bor-
15 der Protection for the fiscal year for which
16 the report is made.

17 (10) SPECIAL RULE REGARDING IMPORTATION
18 BY INDIVIDUALS.—

19 (A) IN GENERAL.—Notwithstanding any
20 provision of this title (or an amendment made
21 by this title), the Secretary shall expedite the
22 designation of any additional countries from
23 which an individual may import a qualifying
24 drug into the United States under such section
25 804 if any action implemented by the Govern-

1 ment of Canada has the effect of limiting or
2 prohibiting the importation of qualifying drugs
3 into the United States from Canada.

4 (B) TIMING AND CRITERIA.—The Sec-
5 retary shall designate such additional countries
6 under subparagraph (A)—

7 (i) not later than 6 months after the
8 date of the action by the Government of
9 Canada described under such subpara-
10 graph; and

11 (ii) using the criteria described under
12 subsection (a)(4)(D)(i)(II) of such section
13 804.

14 (f) IMPLEMENTATION OF SECTION 804.—

15 (1) INTERIM RULE.—The Secretary may pro-
16 mulgate an interim rule for implementing section
17 804 of the Federal Food, Drug, and Cosmetic Act,
18 as added by subsection (a) of this section.

19 (2) NO NOTICE OF PROPOSED RULEMAKING.—
20 The interim rule described under paragraph (1) may
21 be developed and promulgated by the Secretary with-
22 out providing general notice of proposed rulemaking.

23 (3) FINAL RULE.—Not later than 1 year after
24 the date on which the Secretary promulgates an in-
25 terim rule under paragraph (1), the Secretary shall,

1 in accordance with procedures under section 553 of
2 title 5, United States Code, promulgate a final rule
3 for implementing such section 804, which may incor-
4 porate by reference provisions of the interim rule
5 provided for under paragraph (1), to the extent that
6 such provisions are not modified.

7 (g) CONSUMER EDUCATION.—The Secretary shall
8 carry out activities that educate consumers—

9 (1) with regard to the availability of qualifying
10 drugs for import for personal use from an exporter
11 registered with and approved by the Food and Drug
12 Administration under section 804 of the Federal
13 Food, Drug, and Cosmetic Act, as added by this sec-
14 tion, including information on how to verify whether
15 an exporter is registered and approved by use of the
16 Internet website of the Food and Drug Administra-
17 tion and the toll-free telephone number required by
18 this title;

19 (2) that drugs that consumers attempt to im-
20 port from an exporter that is not registered with and
21 approved by the Food and Drug Administration can
22 be seized by the United States Customs Service and
23 destroyed, and that such drugs may be counterfeit,
24 unapproved, unsafe, or ineffective;

1 (3) with regard to the suspension and termi-
2 nation of any registration of a registered importer or
3 exporter under such section 804; and

4 (4) with regard to the availability at domestic
5 retail pharmacies of qualifying drugs imported under
6 such section 804 by domestic wholesalers and phar-
7 macies registered with and approved by the Food
8 and Drug Administration.

9 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-
10 withstanding any provision of this title (and the amend-
11 ments made by this title), the practices and policies of the
12 Food and Drug Administration and Bureau of Customs
13 and Border Protection, in effect on January 1, 2004, with
14 respect to the importation of prescription drugs into the
15 United States by an individual, on the person of such indi-
16 vidual, for personal use, shall remain in effect.

17 (i) REPORT TO CONGRESS.—The Federal Trade
18 Commission shall, on an annual basis, submit to Congress
19 a report that describes any action taken during the period
20 for which the report is being prepared to enforce the provi-
21 sions of section 804(n) of the Federal Food, Drug, and
22 Cosmetic Act (as added by this title), including any pend-
23 ing investigations or civil actions under such section.

1 **SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
2 **SION INTO UNITED STATES.**

3 (a) IN GENERAL.—Chapter VIII of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
5 as amended by section 804, is further amended by adding
6 at the end the following section:

7 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
8 **MISSION.**

9 “(a) IN GENERAL.—The Secretary of Homeland Se-
10 curity shall deliver to the Secretary a shipment of drugs
11 that is imported or offered for import into the United
12 States if—

13 “(1) the shipment has a declared value of less
14 than \$10,000; and

15 “(2)(A) the shipping container for such drugs
16 does not bear the markings required under section
17 804(d)(2); or

18 “(B) the Secretary has requested delivery of
19 such shipment of drugs.

20 “(b) NO BOND OR EXPORT.—Section 801(b) does
21 not authorize the delivery to the owner or consignee of
22 drugs delivered to the Secretary under subsection (a) pur-
23 suant to the execution of a bond, and such drugs may not
24 be exported.

25 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
26 Secretary shall destroy a shipment of drugs delivered by

1 the Secretary of Homeland Security to the Secretary
2 under subsection (a) if—

3 “(1) in the case of drugs that are imported or
4 offered for import from a registered exporter under
5 section 804, the drugs are in violation of any stand-
6 ard described in section 804(g)(5); or

7 “(2) in the case of drugs that are not imported
8 or offered for import from a registered exporter
9 under section 804, the drugs are in violation of a
10 standard referred to in section 801(a) or 801(d)(1).

11 “(d) CERTAIN PROCEDURES.—

12 “(1) IN GENERAL.—The delivery and destruc-
13 tion of drugs under this section may be carried out
14 without notice to the importer, owner, or consignee
15 of the drugs except as required by section 801(g) or
16 section 804(i)(2). The issuance of receipts for the
17 drugs, and recordkeeping activities regarding the
18 drugs, may be carried out on a summary basis.

19 “(2) OBJECTIVE OF PROCEDURES.—Procedures
20 promulgated under paragraph (1) shall be designed
21 toward the objective of ensuring that, with respect to
22 efficiently utilizing Federal resources available for
23 carrying out this section, a substantial majority of
24 shipments of drugs subject to described in sub-
25 section (c) are identified and destroyed.

1 “(e) EVIDENCE EXCEPTION.—Drugs may not be de-
 2 stroyed under subsection (c) to the extent that the Attor-
 3 ney General of the United States determines that the
 4 drugs should be preserved as evidence or potential evi-
 5 dence with respect to an offense against the United States.

6 “(f) RULE OF CONSTRUCTION.—This section may
 7 not be construed as having any legal effect on applicable
 8 law with respect to a shipment of drugs that is imported
 9 or offered for import into the United States and has a
 10 declared value equal to or greater than \$10,000.”.

11 (b) PROCEDURES.—Procedures for carrying out sec-
 12 tion 805 of the Federal Food, Drug, and Cosmetic Act,
 13 as added by subsection (a), shall be established not later
 14 than 90 days after the date of the enactment of this title.

15 (c) EFFECTIVE DATE.—The amendments made by
 16 this section shall take effect on the date that is 90 days
 17 after the date of enactment of this title.

18 **SEC. 806. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
 19 **MENTS REGARDING PRIOR SALE, PURCHASE,**
 20 **OR TRADE.**

21 (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO
 22 REGISTERED EXPORTERS.—Section 503(e) of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is
 24 amended—

25 (1) in paragraph (1)—

1 (A) by striking “and who is not the manu-
2 facturer or an authorized distributor of record
3 of such drug”;

4 (B) by striking “to an authorized dis-
5 tributor of record or”; and

6 (C) by striking subparagraph (B) and in-
7 serting the following:

8 “(B) The fact that a drug subject to subsection (b)
9 is exported from the United States does not with respect
10 to such drug exempt any person that is engaged in the
11 business of the wholesale distribution of the drug from
12 providing the statement described in subparagraph (A) to
13 the person that receives the drug pursuant to the export
14 of the drug.

15 “(C)(i) The Secretary shall by regulation establish re-
16 quirements that supersede subparagraph (A) (referred to
17 in this subparagraph as ‘alternative requirements’) to
18 identify the chain of custody of a drug subject to sub-
19 section (b) from the manufacturer of the drug throughout
20 the wholesale distribution of the drug to a pharmacist who
21 intends to sell the drug at retail if the Secretary deter-
22 mines that the alternative requirements, which may in-
23 clude standardized anti-counterfeiting or track-and-trace
24 technologies, will identify such chain of custody or the
25 identity of the discrete package of the drug from which

1 the drug is dispensed with equal or greater certainty to
2 the requirements of subparagraph (A), and that the alter-
3 native requirements are economically and technically fea-
4 sible.

5 “(ii) When the Secretary promulgates a final rule to
6 establish such alternative requirements, the final rule in
7 addition shall, with respect to the registration condition
8 established in clause (i) of section 804(c)(3)(B), establish
9 a condition equivalent to the alternative requirements, and
10 such equivalent condition may be met in lieu of the reg-
11 istration condition established in such clause (i).”;

12 (2) in paragraph (2)(A), by adding at the end
13 the following: “The preceding sentence may not be
14 construed as having any applicability with respect to
15 a registered exporter under section 804.”; and

16 (3) in paragraph (3), by striking “and sub-
17 section (d)—” in the matter preceding subparagraph
18 (A) and all that follows through “the term ‘whole-
19 sale distribution’ means” in subparagraph (B) and
20 inserting the following: “and subsection (d), the
21 term ‘wholesale distribution’ means”.

22 (b) CONFORMING AMENDMENT.—Section 503(d) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 353(d)) is amended by adding at the end the following:

1 “(4) Each manufacturer of a drug subject to sub-
2 section (b) shall maintain at its corporate offices a current
3 list of the authorized distributors of record of such drug.

4 “(5) For purposes of this subsection, the term ‘au-
5 thorized distributors of record’ means those distributors
6 with whom a manufacturer has established an ongoing re-
7 lationship to distribute such manufacturer’s products.”.

8 (c) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The amendments made by
10 paragraphs (1) and (3) of subsection (a) and by sub-
11 section (b) shall take effect on January 1, 2010.

12 (2) DRUGS IMPORTED BY REGISTERED IMPORT-
13 ERS UNDER SECTION 804.—Notwithstanding para-
14 graph (1), the amendments made by paragraphs (1)
15 and (3) of subsection (a) and by subsection (b) shall
16 take effect on the date that is 90 days after the date
17 of enactment of this title with respect to qualifying
18 drugs imported under section 804 of the Federal
19 Food, Drug, and Cosmetic Act, as added by section
20 804.

21 (3) EFFECT WITH RESPECT TO REGISTERED
22 EXPORTERS.—The amendment made by subsection
23 (a)(2) shall take effect on the date that is 90 days
24 after the date of enactment of this title.

1 (4) ALTERNATIVE REQUIREMENTS.—The Sec-
2 retary shall issue regulations to establish the alter-
3 native requirements, referred to in the amendment
4 made by subsection (a)(1), that take effect not later
5 than January 1, 2010.

6 (5) INTERMEDIATE REQUIREMENTS.—The Sec-
7 retary shall by regulation require the use of stand-
8 ardized anti-counterfeiting or track-and-trace tech-
9 nologies on prescription drugs at the case and pallet
10 level effective not later than 1 year after the date of
11 enactment of this title.

12 (6) ADDITIONAL REQUIREMENTS.—

13 (A) IN GENERAL.—Notwithstanding any
14 other provision of this section, the Secretary
15 shall, not later than 18 months after the date
16 of enactment of this title, require that the pack-
17 aging of any prescription drug incorporates—

18 (i) a standardized numerical identifier
19 unique to each package of such drug, ap-
20 plied at the point of manufacturing and re-
21 packaging (in which case the numerical
22 identifier shall be linked to the numerical
23 identifier applied at the point of manufac-
24 turing); and

1 (ii)(I) overt optically variable counter-
2 feit-resistant technologies that—

3 (aa) are visible to the naked eye,
4 providing for visual identification of
5 product authenticity without the need
6 for readers, microscopes, lighting de-
7 vices, or scanners;

8 (bb) are similar to that used by
9 the Bureau of Engraving and Printing
10 to secure United States currency;

11 (cc) are manufactured and dis-
12 tributed in a highly secure, tightly
13 controlled environment; and

14 (dd) incorporate additional layers
15 of nonvisible covert security features
16 up to and including forensic capa-
17 bility, as described in subparagraph
18 (B); or

19 (II) technologies that have a function
20 of security comparable to that described in
21 subclause (I), as determined by the Sec-
22 retary.

23 (B) STANDARDS FOR PACKAGING.—For
24 the purpose of making it more difficult to coun-
25 terfeit the packaging of drugs subject to this

1 paragraph, the manufacturers of such drugs
2 shall incorporate the technologies described in
3 subparagraph (A) into at least 1 additional ele-
4 ment of the physical packaging of the drugs, in-
5 cluding blister packs, shrink wrap, package la-
6 bels, package seals, bottles, and boxes.

7 **SEC. 807. INTERNET SALES OF PRESCRIPTION DRUGS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
10 ed by inserting after section 503A the following:

11 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

12 “(a) REQUIREMENTS REGARDING INFORMATION ON
13 INTERNET SITE.—

14 “(1) IN GENERAL.—A person may not dispense
15 a prescription drug pursuant to a sale of the drug
16 by such person if—

17 “(A) the purchaser of the drug submitted
18 the purchase order for the drug, or conducted
19 any other part of the sales transaction for the
20 drug, through an Internet site;

21 “(B) the person dispenses the drug to the
22 purchaser by mailing or shipping the drug to
23 the purchaser; and

24 “(C) such site, or any other Internet site
25 used by such person for purposes of sales of a

1 prescription drug, fails to meet each of the re-
2 quirements specified in paragraph (2), other
3 than a site or pages on a site that—

4 “(i) are not intended to be accessed
5 by purchasers or prospective purchasers; or

6 “(ii) provide an Internet information
7 location tool within the meaning of section
8 231(e)(5) of the Communications Act of
9 1934 (47 U.S.C. 231(e)(5)).

10 “(2) REQUIREMENTS.—With respect to an
11 Internet site, the requirements referred to in sub-
12 paragraph (C) of paragraph (1) for a person to
13 whom such paragraph applies are as follows:

14 “(A) Each page of the site shall include ei-
15 ther the following information or a link to a
16 page that provides the following information:

17 “(i) The name of such person.

18 “(ii) Each State in which the person
19 is authorized by law to dispense prescrip-
20 tion drugs.

21 “(iii) The address and telephone num-
22 ber of each place of business of the person
23 with respect to sales of prescription drugs
24 through the Internet, other than a place of

1 business that does not mail or ship pre-
2 scription drugs to purchasers.

3 “(iv) The name of each individual who
4 serves as a pharmacist for prescription
5 drugs that are mailed or shipped pursuant
6 to the site, and each State in which the in-
7 dividual is authorized by law to dispense
8 prescription drugs.

9 “(v) If the person provides for medical
10 consultations through the site for purposes
11 of providing prescriptions, the name of
12 each individual who provides such con-
13 sultations; each State in which the indi-
14 vidual is licensed or otherwise authorized
15 by law to provide such consultations or
16 practice medicine; and the type or types of
17 health professions for which the individual
18 holds such licenses or other authorizations.

19 “(B) A link to which paragraph (1) applies
20 shall be displayed in a clear and prominent
21 place and manner, and shall include in the cap-
22 tion for the link the words ‘licensing and con-
23 tact information’.

24 “(b) INTERNET SALES WITHOUT APPROPRIATE
25 MEDICAL RELATIONSHIPS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), a person may not dispense a prescription
3 drug, or sell such a drug, if—

4 “(A) for purposes of such dispensing or
5 sale, the purchaser communicated with the per-
6 son through the Internet;

7 “(B) the patient for whom the drug was
8 dispensed or purchased did not, when such
9 communications began, have a prescription for
10 the drug that is valid in the United States;

11 “(C) pursuant to such communications, the
12 person provided for the involvement of a practi-
13 tioner, or an individual represented by the per-
14 son as a practitioner, and the practitioner or
15 such individual issued a prescription for the
16 drug that was purchased;

17 “(D) the person knew, or had reason to
18 know, that the practitioner or the individual re-
19 ferred to in subparagraph (C) did not, when
20 issuing the prescription, have a qualifying med-
21 ical relationship with the patient; and

22 “(E) the person received payment for the
23 dispensing or sale of the drug.

1 For purposes of subparagraph (E), payment is re-
2 ceived if money or other valuable consideration is re-
3 ceived.

4 “(2) EXCEPTIONS.—Paragraph (1) does not
5 apply to—

6 “(A) the dispensing or selling of a pre-
7 scription drug pursuant to telemedicine prac-
8 tices sponsored by—

9 “(i) a hospital that has in effect a
10 provider agreement under title XVIII of
11 the Social Security Act (relating to the
12 Medicare program); or

13 “(ii) a group practice that has not
14 fewer than 100 physicians who have in ef-
15 fect provider agreements under such title;
16 or

17 “(B) the dispensing or selling of a pre-
18 scription drug pursuant to practices that pro-
19 mote the public health, as determined by the
20 Secretary by regulation.

21 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

22 “(A) IN GENERAL.—With respect to
23 issuing a prescription for a drug for a patient,
24 a practitioner has a qualifying medical relation-

1 ship with the patient for purposes of this sec-
2 tion if—

3 “(i) at least one in-person medical
4 evaluation of the patient has been con-
5 ducted by the practitioner; or

6 “(ii) the practitioner conducts a med-
7 ical evaluation of the patient as a covering
8 practitioner.

9 “(B) IN-PERSON MEDICAL EVALUATION.—

10 A medical evaluation by a practitioner is an in-
11 person medical evaluation for purposes of this
12 section if the practitioner is in the physical
13 presence of the patient as part of conducting
14 the evaluation, without regard to whether por-
15 tions of the evaluation are conducted by other
16 health professionals.

17 “(C) COVERING PRACTITIONER.—With re-
18 spect to a patient, a practitioner is a covering
19 practitioner for purposes of this section if the
20 practitioner conducts a medical evaluation of
21 the patient at the request of a practitioner who
22 has conducted at least one in-person medical
23 evaluation of the patient and is temporarily un-
24 available to conduct the evaluation of the pa-
25 tient. A practitioner is a covering practitioner

1 without regard to whether the practitioner has
2 conducted any in-person medical evaluation of
3 the patient involved.

4 “(4) RULES OF CONSTRUCTION.—

5 “(A) INDIVIDUALS REPRESENTED AS
6 PRACTITIONERS.—A person who is not a practi-
7 tioner (as defined in subsection (e)(1)) lacks
8 legal capacity under this section to have a
9 qualifying medical relationship with any patient.

10 “(B) STANDARD PRACTICE OF PHAR-
11 MACY.—Paragraph (1) may not be construed as
12 prohibiting any conduct that is a standard prac-
13 tice in the practice of pharmacy.

14 “(C) APPLICABILITY OF REQUIRE-
15 MENTS.—Paragraph (3) may not be construed
16 as having any applicability beyond this section,
17 and does not affect any State law, or interpre-
18 tation of State law, concerning the practice of
19 medicine.

20 “(c) ACTIONS BY STATES.—

21 “(1) IN GENERAL.—Whenever an attorney gen-
22 eral of any State has reason to believe that the in-
23 terests of the residents of that State have been or
24 are being threatened or adversely affected because
25 any person has engaged or is engaging in a pattern

1 or practice that violates section 301(l), the State
2 may bring a civil action on behalf of its residents in
3 an appropriate district court of the United States to
4 enjoin such practice, to enforce compliance with such
5 section (including a nationwide injunction), to obtain
6 damages, restitution, or other compensation on be-
7 half of residents of such State, to obtain reasonable
8 attorneys fees and costs if the State prevails in the
9 civil action, or to obtain such further and other relief
10 as the court may deem appropriate.

11 “(2) NOTICE.—The State shall serve prior writ-
12 ten notice of any civil action under paragraph (1) or
13 (5)(B) upon the Secretary and provide the Secretary
14 with a copy of its complaint, except that if it is not
15 feasible for the State to provide such prior notice,
16 the State shall serve such notice immediately upon
17 instituting such action. Upon receiving a notice re-
18 specting a civil action, the Secretary shall have the
19 right—

20 “(A) to intervene in such action;

21 “(B) upon so intervening, to be heard on
22 all matters arising therein; and

23 “(C) to file petitions for appeal.

24 “(3) CONSTRUCTION.—For purposes of bring-
25 ing any civil action under paragraph (1), nothing in

1 this chapter shall prevent an attorney general of a
2 State from exercising the powers conferred on the
3 attorney general by the laws of such State to con-
4 duct investigations or to administer oaths or affir-
5 mations or to compel the attendance of witnesses or
6 the production of documentary and other evidence.

7 “(4) VENUE; SERVICE OF PROCESS.—Any civil
8 action brought under paragraph (1) in a district
9 court of the United States may be brought in the
10 district in which the defendant is found, is an inhab-
11 itant, or transacts business or wherever venue is
12 proper under section 1391 of title 28, United States
13 Code. Process in such an action may be served in
14 any district in which the defendant is an inhabitant
15 or in which the defendant may be found.

16 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

17 “(A) Nothing contained in this section
18 shall prohibit an authorized State official from
19 proceeding in State court on the basis of an al-
20 leged violation of any civil or criminal statute of
21 such State.

22 “(B) In addition to actions brought by an
23 attorney general of a State under paragraph
24 (1), such an action may be brought by officers
25 of such State who are authorized by the State

1 to bring actions in such State on behalf of its
2 residents.

3 “(d) EFFECT OF SECTION.—This section shall not
4 apply to a person that is a registered exporter under sec-
5 tion 804.

6 “(e) GENERAL DEFINITIONS.—For purposes of this
7 section:

8 “(1) The term ‘practitioner’ means a practi-
9 tioner referred to in section 503(b)(1) with respect
10 to issuing a written or oral prescription.

11 “(2) The term ‘prescription drug’ means a drug
12 that is described in section 503(b)(1).

13 “(3) The term ‘qualifying medical relationship’,
14 with respect to a practitioner and a patient, has the
15 meaning indicated for such term in subsection (b).

16 “(f) INTERNET-RELATED DEFINITIONS.—

17 “(1) IN GENERAL.—For purposes of this sec-
18 tion:

19 “(A) The term ‘Internet’ means collectively
20 the myriad of computer and telecommunications
21 facilities, including equipment and operating
22 software, which comprise the interconnected
23 world-wide network of networks that employ the
24 transmission control protocol/internet protocol,
25 or any predecessor or successor protocols to

1 such protocol, to communicate information of
2 all kinds by wire or radio.

3 “(B) The term ‘link’, with respect to the
4 Internet, means one or more letters, words,
5 numbers, symbols, or graphic items that appear
6 on a page of an Internet site for the purpose
7 of serving, when activated, as a method for exe-
8 cuting an electronic command—

9 “(i) to move from viewing one portion
10 of a page on such site to another portion
11 of the page;

12 “(ii) to move from viewing one page
13 on such site to another page on such site;
14 or

15 “(iii) to move from viewing a page on
16 one Internet site to a page on another
17 Internet site.

18 “(C) The term ‘page’, with respect to the
19 Internet, means a document or other file
20 accessed at an Internet site.

21 “(D)(i) The terms ‘site’ and ‘address’, with
22 respect to the Internet, mean a specific location
23 on the Internet that is determined by Internet
24 Protocol numbers. Such term includes the do-
25 main name, if any.

1 “(ii) The term ‘domain name’ means a
2 method of representing an Internet address
3 without direct reference to the Internet Protocol
4 numbers for the address, including methods
5 that use designations such as ‘.com’, ‘.edu’,
6 ‘.gov’, ‘.net’, or ‘.org’.

7 “(iii) The term ‘Internet Protocol num-
8 bers’ includes any successor protocol for deter-
9 mining a specific location on the Internet.

10 “(2) AUTHORITY OF SECRETARY.—The Sec-
11 retary may by regulation modify any definition
12 under paragraph (1) to take into account changes in
13 technology.

14 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
15 TISING.—No provider of an interactive computer service,
16 as defined in section 230(f)(2) of the Communications Act
17 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
18 shall be liable under this section for dispensing or selling
19 prescription drugs in violation of this section on account
20 of another person’s selling or dispensing such drugs, pro-
21 vided that the provider of the interactive computer service
22 or of advertising services does not own or exercise cor-
23 porate control over such person.”.

24 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
25 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 331) is amended by inserting after paragraph (k) the fol-
2 lowing:

3 “(l) The dispensing or selling of a prescription drug
4 in violation of section 503B.”.

5 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
6 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
7 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
8 NESSES.—In carrying out section 503B of the Federal
9 Food, Drug, and Cosmetic Act (as added by subsection
10 (a) of this section), the Secretary of Health and Human
11 Services shall take into consideration the practices and
12 procedures of public or private entities that certify that
13 businesses selling prescription drugs through Internet
14 sites are legitimate businesses, including practices and
15 procedures regarding disclosure formats and verification
16 programs.

17 (d) REPORTS REGARDING INTERNET-RELATED VIO-
18 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
19 OF DRUGS.—

20 (1) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this subsection as
22 the “Secretary”) shall, pursuant to the submission
23 of an application meeting the criteria of the Sec-
24 retary, make an award of a grant or contract to the
25 National Clearinghouse on Internet Prescribing (op-

erated by the Federation of State Medical Boards)
for the purpose of—

(A) identifying Internet sites that appear
to be in violation of Federal or State laws con-
cerning the dispensing of drugs;

(B) reporting such sites to State medical
licensing boards and State pharmacy licensing
boards, and to the Attorney General and the
Secretary, for further investigation; and

(C) submitting, for each fiscal year for
which the award under this subsection is made,
a report to the Secretary describing investiga-
tions undertaken with respect to violations de-
scribed in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For
the purpose of carrying out paragraph (1), there is
authorized to be appropriated \$100,000 for each of
the first 3 fiscal years in which this section is in ef-
fect.

(e) EFFECTIVE DATE.—The amendments made by
subsections (a) and (b) take effect 90 days after the date
of enactment of this title, without regard to whether a
final rule to implement such amendments has been pro-
mulgated by the Secretary of Health and Human Services
under section 701(a) of the Federal Food, Drug, and Cos-

1 metic Act. The preceding sentence may not be construed
 2 as affecting the authority of such Secretary to promulgate
 3 such a final rule.

4 **SEC. 808. PROHIBITING PAYMENTS TO UNREGISTERED**
 5 **FOREIGN PHARMACIES.**

6 (a) IN GENERAL.—Section 303 of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
 8 adding at the end the following:

9 “(g) RESTRICTED TRANSACTIONS.—

10 “(1) IN GENERAL.—The introduction of re-
 11 stricted transactions into a payment system or the
 12 completion of restricted transactions using a pay-
 13 ment system is prohibited.

14 “(2) PAYMENT SYSTEM.—

15 “(A) IN GENERAL.—The term ‘payment
 16 system’ means a system used by a person de-
 17 scribed in subparagraph (B) to effect a credit
 18 transaction, electronic fund transfer, or money
 19 transmitting service that may be used in con-
 20 nection with, or to facilitate, a restricted trans-
 21 action, and includes—

22 “(i) a credit card system;

23 “(ii) an international, national, re-
 24 gional, or local network used to effect a
 25 credit transaction, an electronic fund

1 transfer, or a money transmitting service;

2 and

3 “(iii) any other system that is cen-
4 trally managed and is primarily engaged in
5 the transmission and settlement of credit
6 transactions, electronic fund transfers, or
7 money transmitting services.

8 “(B) PERSONS DESCRIBED.—A person re-
9 ferred to in subparagraph (A) is—

10 “(i) a creditor;

11 “(ii) a credit card issuer;

12 “(iii) a financial institution;

13 “(iv) an operator of a terminal at
14 which an electronic fund transfer may be
15 initiated;

16 “(v) a money transmitting business;

17 or

18 “(vi) a participant in an international,
19 national, regional, or local network used to
20 effect a credit transaction, electronic fund
21 transfer, or money transmitting service.

22 “(3) RESTRICTED TRANSACTION.—The term
23 ‘restricted transaction’ means a transaction or trans-
24 mittal, on behalf of an individual who places an un-
25 lawful drug importation request to any person en-

1 gaged in the operation of an unregistered foreign
2 pharmacy, of—

3 “(A) credit, or the proceeds of credit, ex-
4 tended to or on behalf of the individual for the
5 purpose of the unlawful drug importation re-
6 quest (including credit extended through the
7 use of a credit card);

8 “(B) an electronic fund transfer or funds
9 transmitted by or through a money transmit-
10 ting business, or the proceeds of an electronic
11 fund transfer or money transmitting service,
12 from or on behalf of the individual for the pur-
13 pose of the unlawful drug importation request;

14 “(C) a check, draft, or similar instrument
15 which is drawn by or on behalf of the individual
16 for the purpose of the unlawful drug importa-
17 tion request and is drawn on or payable at or
18 through any financial institution; or

19 “(D) the proceeds of any other form of fi-
20 nancial transaction (identified by the Board by
21 regulation) that involves a financial institution
22 as a payor or financial intermediary on behalf
23 of or for the benefit of the individual for the
24 purpose of the unlawful drug importation re-
25 quest.

1 “(4) UNLAWFUL DRUG IMPORTATION RE-
2 QUEST.—The term ‘unlawful drug importation re-
3 quest’ means the request, or transmittal of a re-
4 quest, made to an unregistered foreign pharmacy for
5 a prescription drug by mail (including a private car-
6 rier), facsimile, phone, or electronic mail, or by a
7 means that involves the use, in whole or in part, of
8 the Internet.

9 “(5) UNREGISTERED FOREIGN PHARMACY.—
10 The term ‘unregistered foreign pharmacy’ means a
11 person in a country other than the United States
12 that is not a registered exporter under section 804.

13 “(6) OTHER DEFINITIONS.—

14 “(A) CREDIT; CREDITOR; CREDIT CARD.—
15 The terms ‘credit’, ‘creditor’, and ‘credit card’
16 have the meanings given the terms in section
17 103 of the Truth in Lending Act (15 U.S.C.
18 1602).

19 “(B) ACCESS DEVICE; ELECTRONIC FUND
20 TRANSFER.—The terms ‘access device’ and
21 ‘electronic fund transfer’—

22 “(i) have the meaning given the term
23 in section 903 of the Electronic Fund
24 Transfer Act (15 U.S.C. 1693a); and

1 “(ii) the term ‘electronic fund trans-
 2 fer’ also includes any fund transfer covered
 3 under Article 4A of the Uniform Commer-
 4 cial Code, as in effect in any State.

5 “(C) FINANCIAL INSTITUTION.—The term
 6 ‘financial institution’—

7 “(i) has the meaning given the term
 8 in section 903 of the Electronic Transfer
 9 Fund Act (15 U.S.C. 1693a); and

10 “(ii) includes a financial institution
 11 (as defined in section 509 of the Gramm-
 12 Leach-Bliley Act (15 U.S.C. 6809)).

13 “(D) MONEY TRANSMITTING BUSINESS;
 14 MONEY TRANSMITTING SERVICE.—The terms
 15 ‘money transmitting business’ and ‘money
 16 transmitting service’ have the meaning given
 17 the terms in section 5330(d) of title 31, United
 18 States Code.

19 “(E) BOARD.—The term ‘Board’ means
 20 the Board of Governors of the Federal Reserve
 21 System.

22 “(7) POLICIES AND PROCEDURES REQUIRED TO
 23 PREVENT RESTRICTED TRANSACTIONS.—

24 “(A) REGULATIONS.—The Board shall
 25 promulgate regulations requiring—

1 “(i) an operator of a credit card sys-
2 tem;

3 “(ii) an operator of an international,
4 national, regional, or local network used to
5 effect a credit transaction, an electronic
6 fund transfer, or a money transmitting
7 service;

8 “(iii) an operator of any other pay-
9 ment system that is centrally managed and
10 is primarily engaged in the transmission
11 and settlement of credit transactions, elec-
12 tronic transfers or money transmitting
13 services where at least one party to the
14 transaction or transfer is an individual;
15 and

16 “(iv) any other person described in
17 paragraph (2)(B) and specified by the
18 Board in such regulations,

19 to establish policies and procedures that are
20 reasonably designed to prevent the introduction
21 of a restricted transaction into a payment sys-
22 tem or the completion of a restricted trans-
23 action using a payment system

1 “(B) REQUIREMENTS FOR POLICIES AND
2 PROCEDURES.—In promulgating regulations
3 under subparagraph (A), the Board shall—

4 “(i) identify types of policies and pro-
5 cedures, including nonexclusive examples,
6 that shall be considered to be reasonably
7 designed to prevent the introduction of re-
8 stricted transactions into a payment sys-
9 tem or the completion of restricted trans-
10 actions using a payment system; and

11 “(ii) to the extent practicable, permit
12 any payment system, or person described
13 in paragraph (2)(B), as applicable, to
14 choose among alternative means of pre-
15 venting the introduction or completion of
16 restricted transactions.

17 “(C) NO LIABILITY FOR BLOCKING OR RE-
18 FUSING TO HONOR RESTRICTED TRANS-
19 ACTION.—

20 “(i) IN GENERAL.—A payment sys-
21 tem, or a person described in paragraph
22 (2)(B) that is subject to a regulation
23 issued under this subsection, and any par-
24 ticipant in such payment system that pre-
25 vents or otherwise refuses to honor trans-

1 actions in an effort to implement the poli-
2 cies and procedures required under this
3 subsection or to otherwise comply with this
4 subsection shall not be liable to any party
5 for such action.

6 “(ii) COMPLIANCE.—A person de-
7 scribed in paragraph (2)(B) meets the re-
8 quirements of this subsection if the person
9 relies on and complies with the policies and
10 procedures of a payment system of which
11 the person is a member or in which the
12 person is a participant, and such policies
13 and procedures of the payment system
14 comply with the requirements of the regu-
15 lations promulgated under subparagraph
16 (A).

17 “(D) ENFORCEMENT.—

18 “(i) IN GENERAL.—This section shall
19 be enforced by the Federal functional regu-
20 lators and the Federal Trade Commission
21 under applicable law in the manner pro-
22 vided in section 505(a) of the Gramm-
23 Leach-Bliley Act (15 U.S.C. 6805(a)).

24 “(ii) FACTORS TO BE CONSIDERED.—
25 In considering any enforcement action

1 under this subsection against a payment
2 system or person described in paragraph
3 (2)(B), the Federal functional regulators
4 and the Federal Trade Commission shall
5 consider the following factors:

6 “(I) The extent to which the pay-
7 ment system or person knowingly per-
8 mits restricted transactions.

9 “(II) The history of the payment
10 system or person in connection with
11 permitting restricted transactions.

12 “(III) The extent to which the
13 payment system or person has estab-
14 lished and is maintaining policies and
15 procedures in compliance with regula-
16 tions prescribed under this subsection.

17 “(8) TRANSACTIONS PERMITTED.—A payment
18 system, or a person described in paragraph (2)(B)
19 that is subject to a regulation issued under this sub-
20 section, is authorized to engage in transactions with
21 foreign pharmacies in connection with investigating
22 violations or potential violations of any rule or re-
23 quirement adopted by the payment system or person
24 in connection with complying with paragraph (7). A
25 payment system, or such a person, and its agents

1 and employees shall not be found to be in violation
2 of, or liable under, any Federal, State or other law
3 by virtue of engaging in any such transaction.

4 “(9) RELATION TO STATE LAWS.—No require-
5 ment, prohibition, or liability may be imposed on a
6 payment system, or a person described in paragraph
7 (2)(B) that is subject to a regulation issued under
8 this subsection, under the laws of any state with re-
9 spect to any payment transaction by an individual
10 because the payment transaction involves a payment
11 to a foreign pharmacy.

12 “(10) TIMING OF REQUIREMENTS.—A payment
13 system, or a person described in paragraph (2)(B)
14 that is subject to a regulation issued under this sub-
15 section, must adopt policies and procedures reason-
16 ably designed to comply with any regulations re-
17 quired under paragraph (7) within 60 days after
18 such regulations are issued in final form.”.

19 (b) EFFECTIVE DATE.—The amendment made by
20 this section shall take effect on the day that is 90 days
21 after the date of enactment of this Act.

22 (c) IMPLEMENTATION.—The Board of Governors of
23 the Federal Reserve System shall promulgate regulations
24 as required by subsection (g)(7) of section 303 of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333), as

1 added by subsection (a), not later than 90 days after the
2 date of enactment of this title.

3 **SEC. 809. IMPORTATION EXEMPTION UNDER CONTROLLED**
4 **SUBSTANCES IMPORT AND EXPORT ACT.**

5 Section 1006(a)(2) of the Controlled Substances Im-
6 port and Export Act (21 U.S.C. 956(a)(2)) is amended
7 by striking “not import the controlled substance into the
8 United States in an amount that exceeds 50 dosage units
9 of the controlled substance.” and inserting “import into
10 the United States not more than 10 dosage units com-
11 bined of all such controlled substances.”.

12 **SEC. 810. SEVERABILITY.**

13 If any provision of this title, an amendment by this
14 title, or the application of such provision or amendment
15 to any person or circumstance is held to be unconstitu-
16 tional, the remainder of this title, the amendments made
17 by this title, and the application of the provisions of such
18 to any person or circumstance shall not affected thereby.

19 **SEC. 811. PROTECTION OF HEALTH AND SAFETY.**

20 This title, and the amendments made by this title,
21 shall become effective only if the Secretary of Health and
22 Human Services certifies to Congress that the implemen-
23 tation of this title (and amendments) will—

24 (1) pose no additional risk to the public’s health
25 and safety; and

- 1 (2) result in a significant reduction in the cost
- 2 of covered products to the American consumer.

Passed the Senate May 9, 2007.

Attest:

Secretary.

110TH CONGRESS
1ST SESSION

S. 1082

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.